UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

FREIDA AARON *et al.*,	)	
	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 1 :13-cv-00301-MRB
	)	
MEDTRONIC SOFAMOR DANEK, USA, Inc., and MEDTRONIC, Inc.,	)	ORAL ARGUMENT REQUESTED
	)	
Defendants.	)	

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS

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TABLE OF CONTENTS

Page

INTRODUCTION AND SUMMARY OF ARGUMENT 1

ARGUMENT 2

I. PLAINTIFFS' CLAIMS ARE EXPRESSLY PREEMPTED BY 21 U.S.C § 360k(a) 2

Plaintiffs' claims are expressly preempted by 21 U.S.C. § 360k(a), because the federal government has established requirements applicable to the Infuse device, and Plaintiffs' claims seek to impose state-law requirements on the device that are different from or in addition to the federal requirements. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

A. No "Presumption" Against Preemption Applies Here 2

Plaintiffs' claims are not saved by a presumption against preemption, because the Supreme Court has rejected application of such a presumption when analyzing the scope of express preemption under 21 U.S.C. § 360k(a) and implied preemption under 21 U.S.C. § 337(a). *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

B. Premarket Approval Imposes "Requirements" On Infuse, Regardless Of How It Is Used Or Promoted 3

Application of § 360k(a) depends only on whether the FDA has imposed requirements on the device at issue, not on the use to which the device is subsequently put or the manner in which it is subsequently promoted. *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979 (E.D. Mo. 2014).

1. PMA requirements attach to the device and all its components 4

Plaintiffs are mistaken when they argue that the FDA's grant of premarket approval to the Infuse device does not impose preemptive federal requirements on the device's bone graft component. Premarket approval extends to all components of an approved device, even when a physician uses the components separately. *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844 (W.D. Tenn. 2015); *Hawkins v. Medtronic, Inc.*, 2014 WL 346622 (E.D. Cal. 2014).

2. PMA requirements attach to devices, not individual uses 6

Plaintiffs' suggestion that application of § 360k(a) depends on how a medical device is used cannot be reconciled with 21 U.S.C. § 360e, which mandates premarket approval for devices rather than uses, 21 U.S.C. § 396, which prohibits the FDA from regulating how approved devices are used, 21 U.S.C. § 360k(a), which preempts state-law requirements regardless how a device is used, or *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), which held that § 360k(a) preempts tort claims arising from off-label use. *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335 (10th Cir. 2015).

3. Allegations of off-label promotion do not affect preemption 10

Plaintiffs' argument that allegations of off-label promotion negate the preemptive effect of premarket approval is inconsistent with the text of 21 U.S.C. § 360k(a) and contrary to the overwhelming weight of authority. *Byrnes v. Small*, 60 F. Supp. 3d 1289 (M.D. Fla. 2015);

TABLE OF CONTENTS
(continued)

Page

Caplinger v. Medtronic, Inc., 921 F. Supp. 2d 1206 (W.D. Okla. 2013); *Scanlon v. Medtronic Sofamor Danek USA, Inc.*, 2014 WL 3737501 (D. Del. 2014).

C. Plaintiffs Have Not Set Forth "Parallel" Claims 12

As Medtronic showed in its opening brief, each of Plaintiffs' claims—with the possible exception of a fraud claim premised on alleged affirmative representations—is preempted by 21 U.S.C. § 360k(a), because each seeks to impose requirements on the Infuse device different from or in addition to the federal requirements established by the FDA's premarket approval of the device. None of Plaintiffs' arguments in opposition undermine that conclusion. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

1. Plaintiffs have not adequately alleged a causal connection between any purported federal violation and their alleged injuries 12

To state a parallel claim that avoids preemption under 21 U.S.C. § 360k(a), Plaintiffs must adequately plead a causal connection between an alleged federal violation and their alleged injuries. Because Plaintiffs have failed to do so, their claims must be dismissed. *Millman v. Medtronic, Inc.*, 2015 WL 778779 (D.N.J. 2015).

2. Allegations of off-label promotion do not give rise to a parallel claim 13

Allegations that Medtronic engaged in off-label promotion do not save Plaintiffs' claims from preemption under 21 U.S.C. § 360k(a). *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012); *Thorn v. Medtronic Sofamor Danek USA, Inc.*, 81 F. Supp. 3d 619 (W. D. Mich. 2015); *Hawkins v. Medtronic, Inc.*, 2014 WL 346622 (E.D. Cal. 2014).

3. Allegations that Medtronic failed to report adverse events to the FDA do not give rise to a parallel claim 15

Medtronic demonstrated in its opening brief that failure-to-warn claims based on an alleged failure to submit adverse-event reports to the FDA are expressly preempted by § 360k(a). Plaintiffs' Opposition does not meaningfully engage with Medtronic's analysis or the authorities it cited. Rather than refute Medtronic's analysis or distinguish the cases rejecting such claims, Plaintiffs simply cite a handful of other cases, one of which is derivative of the others, one of which is inapposite, and another of which directly supports Medtronic's position. Mem. 32–35.

4. Plaintiffs' failure-to-warn claims are expressly preempted..... 17

Because Plaintiffs do not allege that Medtronic failed to provide any of the warnings required by the FDA through the premarket approval process, Plaintiffs' failure-to-warn claims are expressly preempted. *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206 (W.D. Okla. 2013); *Latimer v. Medtronic, Inc.*, 2015 WL 5222644 (Ga. Super. Ct. 2015).

5. Plaintiffs' design-defect and implied-warranty claims are expressly preempted 18

Because Plaintiffs do not allege that the design of the Infuse device was anything other than the

TABLE OF CONTENTS
(continued)

Page

design approved by the FDA through the premarket approval process, Plaintiffs' design-defect and implied-warranty claims—which are indistinguishable under Ohio law—are expressly preempted. *Tompkin v. Philip Morris USA, Inc.*, 362 F.3d 882 (6th Cir. 2004); *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021 (D. Haw. 2014).

6. Plaintiffs' express-warranty claims are expressly preempted 20

Plaintiffs' do not rebut Medtronic's demonstration that their express warranty claims are expressly preempted because, for Plaintiffs to prevail on their warranty claims, a jury would have to find that Infuse was not safe and effective as labeled. *Gavin v. Medtronic, Inc.*, 2013 WL 3791612 (E.D. La. 2013).

7. Plaintiffs cannot avoid § 360k(a) through evasion of Rule 8(a)..... 21

Contrary to Plaintiffs' suggestion, conclusory allegations that Medtronic violated federal law are not sufficient to avoid dismissal under the Federal Rules of Civil Procedure. Fed. R. Civ. P. 8(a); *Ashcroft v. Iqbal*, 556 U.S. 662 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

II. PLAINTIFFS' CLAIMS ARE IMPLIEDLY PREEMPTED 26

Medtronic showed in its opening brief that Plaintiffs' claims are impliedly preempted because they conflict with the FDCA's no-private-right-of-action provision and with the FDA's grant of premarket approval to the Infuse device. None of Plaintiffs' arguments in opposition undermine that conclusion. 21 U.S.C. § 337(a); *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Marsh v. Genentech, Inc.*, 693 F.3d 546 (6th Cir. 2012).

A. Claims Premised On Alleged Violations Of FDA Regulations Are Barred By *Buckman* and 21 U.S.C 26

Plaintiffs argue that their claims avoid preemption under *Buckman* and 21 U.S.C. § 337(a) because their claims are not "fraud-on-the-FDA" claims. Plaintiffs' argument misses the mark, both because *Buckman* is not limited to fraud-on-the-FDA claims, and because, even if *Buckman* were so limited, Plaintiffs' claims are effectively fraud-on-the-FDA claims. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005); *Williams v. Zimmer U.S. Inc.*, 2015 WL 4256249 (E.D.N.C. 2015); *Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026 (D. Ariz. 2014).

1. Claims premised on alleged off-label promotion are impliedly preempted 29

Because the concept of off-label promotion exists solely by virtue of the FDCA and off-label promotion is not the type of conduct that would traditionally give rise to liability under state law, claims based on alleged off-label promotion are impliedly preempted under *Buckman* and 21 U.S.C. § 337(a). *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844 (W.D. Tenn. 2015); *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979 (E.D. Mo. 2014); *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206 (W.D. Okla. 2013).

TABLE OF CONTENTS
(continued)

Page

2. Claims premised on an alleged failure to submit adverse-event reports to the FDA are impliedly preempted 29

Because binding Sixth Circuit authority holds that any claim predicated on an alleged failure to submit reports to the FDA is impliedly preempted by § 337(a) as interpreted by *Buckman*, claims based on an alleged failure to submit adverse-event reports to the FDA are impliedly preempted. *Marsh v. Genetech, Inc.*, 693 F.3d 546 (6th Cir. 2012); *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844 (W.D. Tenn. 2015).

B. Plaintiffs' Claims Conflict With Federal Law..... 31

1. Plaintiffs' design-defect, implied-warranty, and failure-to-warn claims are impliedly preempted..... 31

Plaintiffs' design-defect, implied-warranty, and failure-to-warn claims are impliedly preempted. If Plaintiffs contend that state law required Medtronic to change Infuse's design or labeling without FDA approval, their claims are impliedly preempted under traditional conflict-preemption principles, because federal law affirmatively prohibits manufacturers from changing the design or labeling of PMA-approved devices without obtaining prior or ultimate FDA approval. If Plaintiffs contend that Medtronic had a duty to seek FDA authorization to modify Infuse's design or label, their claims are impliedly preempted because any duty to submit a supplemental PMA application exists solely by virtue of the FDCA and thus may be enforced only by the Federal Government, and because approval of a supplemental PMA application rests within the FDA's discretion. 21 U.S.C. § 360e; 21 C.F.R. § 814.39; *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001); *Pearsall v. Medtronics, Inc.*, 2015 WL 8160888 (E.D.N.Y. 2015); *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844 (W.D. Tenn. 2015); *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694 (W.D. Tenn. 2011).

2. Plaintiffs' warranty claims are impliedly preempted..... 32

Plaintiffs' warranty claims are impliedly preempted, because, to succeed on such claims, Plaintiffs would have to persuade a jury that the Infuse device is not safe and effective, a finding that would be contrary to the FDA's approval of the device, and because warranty claims implicating the safety and effectiveness of a device with premarket approval would interfere with the FDA's regulation of such devices by requiring the device to be safer but less effective than the model approved by the FDA. *Bryant v. Medtronic, Inc.*, 623 F.3d 1200 (8th Cir. 2010); *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206 (W.D. Okla. 2013).

III. PLAINTIFFS' CLAIMS FAIL ON INDEPENDENT GROUNDS..... 33

Each of Plaintiffs' claims fails on grounds other than preemption.

A. Plaintiffs' Common Law Claims Are Barred By The Ohio Products Liability Act..... 33

Plaintiffs do not dispute that the OPLA abrogates common-law claims arising from the design, production, or marketing of a product, yet do not—and cannot—identify any claim in their Complaint brought under the OPLA.

TABLE OF CONTENTS
(continued)

Page

B. Plaintiffs' Strict-Liability And Implied-Warranty Claims Are Barred By Comment k To § 402A of the Restatement (Second) of Torts 34

Comment k to Restatement (Second) of Torts § 402A bars Plaintiffs' strict-liability and implied-warranty claims, because the Infuse device is "unavoidably unsafe" as a matter of law. 21 U.S.C. § 360c(a)(1)(C)(ii); 21 U.S.C. § 360e(d)(1)(B)(ii); 21 U.S.C. § 360j(e); *Brady v. Medtronic, Inc.*, 2014 WL 1377830 (S.D. Fla. 2014).

C. Plaintiffs' Warranty Claims Fail 36

Plaintiffs' warranty claims fail on two independent grounds.

1. Medtronic disclaimed all warranties 36

Infuse's judicially noticeable label establishes that Medtronic disclaimed all warranties. *Ennenga v. Starns*, 677 F.3d 766 (7th Cir. 2012).

2. Plaintiffs do not adequately allege the existence of an express warranty 37

Plaintiffs allege no facts that, if true, would establish the existence of an express warranty. *Becker v. Smith & Nephew, Inc.*, 2015 WL 4647982 (D.N.J. 2015); *Schouest v. Medtronic, Inc.*, 92 F. Supp. 3d 606 (S.D. Tex. 2015).

D. Plaintiffs' Design-Defect Claim Fails Because Plaintiffs Have Not Adequately Alleged A Defect 37

Plaintiffs' failure to identify an alleged defect in the Infuse design requires dismissal of their design-defect claim. *Anderson v. Boston Sci. Corp.*, 2013 WL 632379 (S.D. Ohio 2013).

E. Plaintiffs' Failure-To-Warn Claims Fail For Multiple Reasons 38

Plaintiffs do not deny that they have failed to adequately allege a causal connection between their alleged injuries and Medtronic's alleged failure to warn, and do not refute Medtronic's demonstration that their failure-to-warn claims are barred by the learned intermediary doctrine. 21 U.S.C. § 360e(d)(1)(A); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Aaron v. Durrani*, 2014 WL 996471 (S.D. Ohio 2014).

IV. PLAINTIFFS FRAUD-BASED CLAIMS ARE NOT ADEQUATELY PLEADED 39

Plaintiffs effectively concede that their fraud claims are inadequately pleaded. Fed. R. Civ. P. 9(b); *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873 (6th Cir. 2006); *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844 (W.D. Tenn. 2015); *Aaron v. Durrani*, 2014 WL 996471 (S.D. Ohio 2014); *Knight Indus. & Assocs. v. Euro Herramientas, S.A.U.*, 2013 WL 3773373 (E.D. Mich. 2013).

CONCLUSION 41

TABLE OF AUTHORITIES

Page(s)

CASES

Aaron v. Durrani,
2014 WL 996471 (S.D. Ohio 2014) ..... *passim*

Ali v. Allergan USA, Inc.,
2012 WL 3692396 (E.D. Va. 2012) 21, 24

Anderson v. Boston Scientific Corp.,
2013 WL 632379 (S.D. Ohio 2013) 25, 38

Angeles v. Medtronic, Inc.,
863 N.W.2d 404 (Minn. Ct. App. 2015) 5, 6, 10

Anthony v. Stryker Corp.,
2010 WL 1387790 (N.D. Ohio 2010) 24

Ashcroft v. Iqbal,
556 U.S. 662 (2009) ..... *passim*

Bass v. Stryker Corp.,
669 F.3d 501 (5th Cir. 2012) 21

Bausch v. Stryker Corp.,
630 F.3d 546 (7th Cir. 2010) ..... *passim*

Beavers-Gabriel v. Medtronic, Inc.,
15 F. Supp. 3d 1021 (D. Haw. 2014) ..... *passim*

Becker v. Smith & Nephew, Inc.,
2015 WL 4647982 (D.N.J. 2015) 37

Bell Atlantic Corp. v. Twombly,
550 U.S. 544 (2007) ..... *passim*

Bertini v. Smith & Nephew, Inc.,
2013 WL 6332684 (E.D.N.Y. 2013) 24

Bertini v. Smith & Nephew, Inc.,
8 F. Supp. 3d 246 (E.D.N.Y. 2014) 4, 11

Blankenship v. Medtronic, Inc.,
6 F. Supp. 3d 979 (E.D. Mo. 2014) 3, 29, 30

TABLE OF AUTHORITIES
(continued)

Page(s)

Brady v. Medtronic, Inc.,
2014 WL 1377830 (S.D. Fla. 2014) 36

Bryant v. Medtronic, Inc., 623 F.3d 1200 (8th Cir. 2010) 21, 33

Buckman Co. v. Plaintiffs' Legal Committee,
531 U.S. 341 (2001) ..... *passim*

Byrnes v. Small,
60 F. Supp. 3d 1289 (M.D. Fla. 2015) 11

Cales v. Medtronic, Inc.,
2014 WL 6600018 (Ky. Cir. Ct. 2014) 18, 19

Caplinger v. Medtronic, Inc.,
784 F.3d 1335 (10th Cir. 2015) 2, 7, 8, 14

Caplinger v. Medtronic, Inc.,
921 F. Supp. 2d 1206 (W.D. Okla. 2013) ..... *passim*

Covert v. Stryker Corp.,
2009 WL 2424559 (M.D.N.C. 2009) 24

Cupek v. Medtronic, Inc.,
405 F.3d 421 (6th Cir. 2005) 28

Desai v. Sorin CRM USA, Inc.,
2013 WL 163298 (D.N.J. 2013) 25, 38

Duggan v. Medtronic, Inc.,
840 F. Supp. 2d 466 (D. Mass. 2012) 4

Ennenga v. Starns,
677 F.3d 766 (7th Cir. 2012) 36

Erickson v. Boston Sci. Corp.,
846 F. Supp. 2d 1085 (C.D. Cal. 2011) 12

Ferdinand-Davenport v. Children's Guild,
742 F. Supp. 2d 772 (D. Md. 2010) 12, 33

Franklin v. Medtronic, Inc.,
2010 WL 2543579 (D. Colo. 2010) 22

TABLE OF AUTHORITIES
(continued)

Page(s)

Garcia v. Fed. Nat'l Mortg. Ass'n,
782 F.3d 736 (6th Cir. 2015) 25

Gavin v. Medtronic, Inc.,
2013 WL 3791612 (E.D. La. 2013) 4, 8, 11, 20

Gelber v. Stryker Corp.,
752 F. Supp. 2d 328 (S.D.N.Y. 2010).....24

Gross v. Stryker Corp.,
858 F. Supp. 2d 466 (W.D. Pa. 2012).....4

Hafer v. Medtronic, Inc.,
99 F. Supp. 3d 844 (W.D. Tenn. 2015)..... *passim*

Hawkins v. Medtronic, Inc.,
2014 WL 346622 (E.D. Cal. 2014)..... *passim*

Hawkins v. Medtronic, Inc.,
909 F. Supp. 2d 901 (S.D. Ohio 2012) 16, 20, 21

Hofts v. Howmedica Osteonics Corp.,
597 F. Supp. 2d 830 (S.D. Ind. 2009) 24

Hopkins v. Women's Div., Gen. Bd. of Global Ministries,
284 F. Supp. 2d 15 (D.D.C. 2003) 12, 33

Horowitz v. Stryker Corp.,
613 F. Supp. 2d 271 (E.D.N.Y. 2009) 24

Hosp. Bldg. Co. v. Trs. of Rex Hosp.,
425 U.S. 738 (1976).....23

Houston v. Medtronic, Inc.,
2014 WL 1364455 (C.D. Cal. 2014).....11

Houston v. Medtronic, Inc.,
957 F. Supp. 2d 1166 (C.D. Cal. 2013) 4, 6, 7

Hughes v. Boston Scientific Corp.,
631 F.3d 762 (5th Cir. 2011) 16

TABLE OF AUTHORITIES
(continued)

Page(s)

Ilarraza v. Medtronic, Inc.,
677 F. Supp. 2d 582 (E.D.N.Y. 2009) 24

Kemp v. Medtronic, Inc.,
231 F.3d 216 (6th Cir. 2000) 30

Knight Indus. & Assocs. v. Euro Herramientas, S.A.U.,
2013 WL 3773373 (E.D. Mich. 2013).....41

Kovac v. Superior Dairy, Inc.,
930 F. Supp. 2d 857 (N.D. Ohio 2013).....36

Latimer v. Medtronic, Inc.,
2015 WL 5222644 (Ga. Super. Ct. 2015)..... *passim*

Ledet v. Medtronic, Inc.,
2013 WL 6858858 (S.D. Miss. 2013).....4, 11

Leonard v. Medtronic Inc.,
2011 WL 3652311 (N.D. Ga. 2011) 24

Loza v. Mitchell,
2011 WL 1236602 (S.D. Ohio 2011).....30

Marsh v. Genetech, Inc.,
693 F.3d 546 (6th Cir. 2012) 30

Martin v. Medtronic, Inc.,
32 F. Supp. 3d 1026 (D. Ariz. 2014) 11, 15, 27

McAffee v. Medtronic, Inc.,
2015 WL 3617755 (N.D. Ind. 2015).....16

McClelland v. Medtronic, Inc.,
944 F. Supp. 2d 1193 (M.D. Fla. 2013).....30

In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.,
592 F. Supp. 2d 1147 (D. Minn. 2009).....21

Medtronic, Inc. v. Lohr,
518 U.S. 470 (1996).....21

TABLE OF AUTHORITIES
(continued)

Page(s)

Millman v. Medtronic, Inc.,
2015 WL 778779 (D.N.J. 2015) 12, 22

Morris v. Johns Manville Int'l, Inc.,
2010 WL 3825867 (E.D. Tenn. 2010) 36

New Albany Tractor, Inc. v. Louisville Tractor, Inc.,
650 F.3d 1046 (6th Cir. 2011) 23, 24, 37

Otis-Wisher v. Medtronic, Inc.,
616 F. App'x 433 (2d Cir. 2015) 2, 14

Parker v. Stryker Corp.,
584 F. Supp. 2d 1298 (D. Colo. 2008).....22

Pearsall v. Medtronic, Inc.,
2015 WL 8160888 (E.D.N.Y. 2015).....32

Perez v. Nidek Co.,
711 F.3d 1109 (9th Cir. 2013) 11, 18

Pinsonneault v. St. Jude Med., Inc.,
953 F. Supp. 2d 1006 (D. Minn. 2013).....30

PLIVA, Inc. v. Mensing,
131 S. Ct. 2567 (2011).....29, 32

In re Porsche Cars N. Am., Inc.,
880 F. Supp. 2d 801 (S.D. Ohio 2012) 19

Purchase v. Advanced Bionics, LLC,
896 F. Supp. 2d 694 (W.D. Tenn. 2011).....5, 10, 32

Ramirez v. Medtronic Inc.,
961 F. Supp. 2d 977 (D. Ariz. 2013) 11

Riegel v. Medtronic, Inc.,
552 U.S. 312 (2008)..... *passim*

Riley v. Cordis Corp.,
625 F. Supp. 2d 769 (D. Minn. 2009).....4, 7, 8, 30

TABLE OF AUTHORITIES
(continued)

Page(s)

Ross v. Abercrombie & Fitch Co.,
257 F.R.D. 435 (S.D. Ohio 2009) 30

Rouse v. Caruso,
2011 WL 918327 (E.D. Mich. 2011) 12, 33

Samet v. Proctor & Gamble Co.,
2013 WL 3124647 (N.D. Cal. 2013) 5

Sanderson v. HCA-The Healthcare Co.,
447 F.3d 873 (6th Cir. 2006) 41

Scanlon v. Medtronic Sofamor Danek USA, Inc.,
64 F. Supp. 3d 403, 411 (D. Del. 2014) 10

Schouest v. Medtronic, Inc.,
92 F. Supp. 3d 606 (S.D. Tex. 2015) 37

Schuler v. Medtronic, Inc.,
2014 WL 988516 (C.D. Cal. 2014) 13

Scovil v. Medtronic Inc.,
2015 WL 880614 (D. Nev. 2015) 16, 36

Smith v. Depuy Orthopedics Inc.,
552 F. App'x 192 (3d Cir. 2014) 4, 26

Smith v. St. Jude Med. Cardiac Rhythm Mgmt. Div.,
2013 WL 1104427 (D. Md. 2013) 26

In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig.,
2004 WL 45503 (D. Minn. 2004) 26

Stengel v. Medtronic, Inc.,
704 F.3d 1224 (9th Cir. 2013) 16

Talbott v. C.R. Bard, Inc.,
63 F.3d 25 (1st Cir. 1995) 10

Thorn v. Medtronic Sofamor Danek USA, Inc.,
81 F. Supp. 3d 619 (W. D. Mich. 2015) 15

TABLE OF AUTHORITIES
(continued)

Page(s)

Tompkin v. Philip Morris USA, Inc.,
362 F.3d 882 (6th Cir. 2004) 18

United States v. Caputo,
517 F.3d 935 (7th Cir. 2008) 14

United States v. Caputo,
288 F. Supp. 2d 912 (N.D. Ill. 2003) 14

United States v. Caronia,
703 F.3d 149 (2d Cir. 2012) 9, 13, 14

United States v. Millennium Pharmaceuticals, Inc.,
No. 2:09-cv-03010 (E.D. Cal.) 14

Wagner v. Roche Labs.,
709 N.E.2d 162 (Ohio 1999) 20

Waltenburg v. St. Jude Medical, Inc.,
33 F. Supp. 3d 818 (W.D. Ky. 2014) 22, 23, 24

Watkins v. Conn,
2015 WL 1927794 (S.D. Ohio 2015) 19

White v. DePuy, Inc.,
718 N.E.3d 450 (Ohio Ct. App. 1998) 18

White v. Stryker Corp.,
818 F. Supp. 2d 1032 (W.D. Ky. 2011) 23

White v. Wyeth Labs., Inc.,
533 N.E.2d 748 (Ohio 1988) 35

Williams v. Zimmer U.S. Inc.,
2015 WL 4256249 (E.D.N.C. 2015) 27

Wolicki-Gables v. Arrow Int'l, Inc.,
634 F.3d 1296 (11th Cir. 2011) 22

Pa. ex rel. Zimmerman v. PepsiCo, Inc.,
836 F.2d 173 (3d Cir. 1988) 19

TABLE OF AUTHORITIES
(continued)

Page(s)

STATUTES, RULES AND REGULATIONS

21 U.S.C. § 321(h) 6

21 U.S.C. § 337(a) 26, 29, 30

21 U.S.C. § 360c(a)(1)(C)(ii) 34

21 U.S.C. § 360e(d)(1)(A) ..... *passim*

21 U.S.C. § 360h 19

21 U.S.C. § 360j(e) 34

21 U.S.C. § 360k ..... *passim*

21 U.S.C. § 396 ..... 3, 7

21 C.F.R. § 801.4 9

21 C.F.R. § 803.50 28

21 C.F.R. § 814.20(b)(8)(ii) 9

21 C.F.R. § 814.39 ..... 28, 31, 32

21 C.F.R. § 820.1 20

21 C.F.R. § 860.7(b)(2) 9

21 C.F.R. § 888.3080(b)(2) 35

Fed. R. Civ. P. 8 ..... *passim*

Fed. R. Civ. P. 9 ..... 39, 40, 41

OTHER AUTHORITIES

72 Fed. Reg. 32,170, 32,171 (June 12, 2007) 34

FDA, Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, 74 F.R. 1694-01 (Jan. 13, 2009) 13

TABLE OF AUTHORITIES
(continued)

Page(s)

Restatement (Second) of Torts § 402A (1965) 34, 36

Use of Approved Drugs for Unlabeled Indications,
12 FDA Drug Bull. 4 (1982).....7

Defendants Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively, "Medtronic") respectfully submit this reply in support of their motion to dismiss Plaintiffs' Fifth Amended Complaint.

INTRODUCTION AND SUMMARY OF ARGUMENT

As another court recently explained when dismissing a complaint arising from alleged off-label promotion of the Infuse device, "[a]lthough the emerging case law is not entirely uniform, there is a clear consensus among the reported cases that claims such as those asserted here are preempted entirely or in large measure." *Latimer v. Medtronic, Inc.*, 2015 WL 5222644, at *6 (Ga. Super. Ct. 2015) (collecting cases). In fact, since this case was filed, dozens of federal and state courts across the country—including the U.S. Courts of Appeals for the Second and Tenth Circuits and two district courts within the Sixth Circuit—have dismissed or affirmed the dismissal of complaints virtually identical to Plaintiffs', holding the claims asserted to be preempted, inadequately pleaded, and/or otherwise legally deficient. *See* Mem. 2–4 (citing cases)

Rather than confront this "clear consensus" (*Latimer*, 2015 WL 5222644, at *6), Plaintiffs ignore it. Indeed, Plaintiffs' Opposition (Opp.) ignores not only the weight of national authority, but most of Medtronic's detailed analysis of why their claims are subject to dismissal on preemption and other grounds. As explained below, to the extent Plaintiffs do respond to Medtronic's analysis, their arguments rely on flawed premises and inapposite cases. Because Plaintiffs have done nothing to refute the arguments set forth in Medtronic's opening brief, this Court should grant Medtronic's motion to dismiss Plaintiffs' Fifth Amended Complaint with prejudice.

ARGUMENT

I. PLAINTIFFS' CLAIMS ARE EXPRESSLY PREEMPTED BY 21 U.S.C. § 360k(a).

Plaintiffs' claims "are expressly preempted under § 360k(a)." *Otis-Wisher v. Medtronic, Inc.*, 616 F. App'x 433, 434 (2d Cir. 2015); *accord Caplinger v. Medtronic, Inc.*, 784 F.3d 1335 (10th Cir. 2015) (*Caplinger II*), *petition for cert. filed*, 84 U.S.L.W. 3123 (U.S. Sept. 11, 2015) (No. 15-321).

In an effort to avoid preemption, Plaintiffs raise a series of spurious arguments about the law governing claims against manufacturers of medical devices that have received Premarket Approval. In fact, application of the test that the U.S. Supreme Court set forth in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), is straightforward and shows that Plaintiffs' claims are expressly preempted. First, the FDA's grant of Premarket Approval to the Infuse device imposes federal "requirements" on the device, Plaintiffs' arguments to the contrary notwithstanding. *See* Mem. 13–14. Second, Plaintiffs' claims would impose state-law requirements "different from, or in addition to" those federal requirements. Plaintiffs' claims are therefore expressly preempted. *See* Mem. 15–20.

A. No "Presumption" Against Preemption Applies Here.

As a threshold matter, there is no presumption against preemption here. Indeed, contrary to Plaintiffs' suggestion that their claims survive under such a "presumption" (Opp. 14–15), "the Supreme Court of the United States has twice ***rejected*** application of such a presumption in the medical-device context." *Latimer*, 2015 WL 5222644, at *4 (emphasis added). In *Riegel*, the Court rejected the dissent's reliance on that presumption, because "the text of [§ 360k(a)]" plainly demonstrates Congress's intent to displace "the tort law of 50 States." 552 U.S. at 326; *see also id.* at 316 (Congress intended the MDA's express preemption clause to "swe[ep] back some state obligations" and replace them with "a regime of detailed federal oversight"); *cf. id.* at

334 (Ginsburg, J., dissenting). And in *Buckman*, the Court held that there is "no presumption against pre-emption" for state-law claims seeking to enforce FDCA requirements. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 347–48 (2001). Thus, "a presumption against preemption does not preclude the preemption of Plaintiff[s'] claims in this case." *Latimer*, 2015 WL 5222644, at *4.

B. Premarket Approval Imposes "Requirements" On Infuse, Regardless Of How It Is Used Or Promoted.

As Medtronic noted in its Memorandum (at 13–14), the Supreme Court has held that "[p]remarket approval … imposes [federal] 'requirements'" within the meaning of 21 U.S.C. § 360k(a). *Riegel*, 552 U.S. at 322–23. And Plaintiffs concede that Infuse received premarket approval in 2002. *See* 5th AC ¶ 414; Opp. 6; *see also* Mem. 7–8. Thus, the question whether the federal government has imposed preemptive requirements on the Infuse device for purposes of § 360k(a) "is easily answered in the affirmative." *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 986 (E.D. Mo. 2014). By its plain terms, § 360k(a) applies whenever the FDA has established "any requirement … applicable *to the device*." 21 U.S.C. § 360k(a)(2) (emphasis added). Accordingly, application of § 360k(a) depends only on whether the FDA has imposed requirements on the device, not on the use to which the device is subsequently put or the manner in which it is subsequently promoted. That is as it must be, because the FDA does not regulate how approved devices are used, a decision committed to doctors' professional judgment. *See id.* § 396. Relying either on no authority at all or on a few aberrational decisions, Plaintiffs advance a number of theories attempting to avoid application of § 360k(a), but each is meritless and should be rejected.[1]

[1] Indeed, this Court has already implicitly rejected Plaintiffs' argument when, in a related case also arising from the alleged off-label promotion of the Infuse device, it concluded that a

1. PMA requirements attach to the device and all its components.

Plaintiffs' primary response to Medtronic's showing that *Riegel*'s first step is satisfied is to assert that the FDA has not established federal requirements for Infuse's rhBMP-2 component when used without the LT-Cage component. But that assertion is incorrect. Premarket approval extends to all components of an approved device, even when a physician uses the components separately. Thus, nearly every court to consider this issue in an Infuse case has held that "premarket approval is as controlling of the individual components … as it is to the device as a whole." *Hawkins v. Medtronic, Inc.*, 2014 WL 346622, at *5 (E.D. Cal. 2014); *accord, e.g.*, *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 858 (W.D. Tenn. 2015); *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1032–33 (D. Haw. 2014); *Ledet v. Medtronic, Inc.*, 2013 WL 6858858, at *3 (S.D. Miss. 2013); *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1176 (C.D. Cal. 2013); *Gavin v. Medtronic, Inc.*, 2013 WL 3791612, at *11–12 (E.D. La. 2013); *Latimer*, 2015 WL 5222644, at *7. Courts addressing other devices have likewise held that claims arising from use of a particular component of a device are "also subject to PMA preemption." *Smith v. Depuy Orthopedics Inc.*, 552 F. App'x 192, 196 (3d Cir. 2014); *accord, e.g.*, *Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 251–55 (E.D.N.Y. 2014); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 487 (W.D. Pa. 2012); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 779 (D. Minn. 2009); *Duggan v. Medtronic, Inc.*, 840 F. Supp. 2d 466, 471 (D. Mass. 2012). There is therefore no doubt that § 360k(a) applies here.

In an attempt to evade the clear authority on this issue, Plaintiffs—citing the FDA-mandated warning that "[t]he Infuse Bone Graft component must not be used without the LT-Cage Lumbar Tapered Fusion Device component"—contend that "[t]he FDA's … approval of

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failure-to-warn claim brought by many of the same Plaintiffs here was preempted by § 360k(a). *See Aaron v. Durrani*, 2014 WL 996471, at *8 n.10 (S.D. Ohio 2014) (Black, J.).

Medtronic's PMA for [Infuse] was expressly restricted to the use of both components together." Opp. 19 (quoting Mem. Ex. 2 (Dkt. No. 61-2), at 1). But Plaintiffs misinterpret an FDA-approved warning to doctors as a non-existent limitation on the scope of the device's premarket approval. And Plaintiffs are wrong when they assert that "there is no label to analyze" for "the bone protein alone." Opp. 20. Because the FDA requires that each component of the Infuse device be sold separately, it has mandated that Infuse's bone-graft component carry *its own warning label*. *Cf.* Mem. Ex. 2 at 1 (noting that the "LT-Cage Lumbar Tapered Fusion Device component is sold separately from the Infuse Bone Graft component" and that "[t]he package labeling for the LT-Cage Lumbar Tapered Fusion Device contains complete product information for this component").

Thus, Plaintiffs are mistaken when they argue that § 360k(a) does not apply here because Plaintiffs' doctors sometimes used Infuse's rhBMP-2 component alone or with a cage other than the LT-Cage. *See* Opp. 20. As is apparent from Plaintiffs' brief, which relies exclusively on two inapposite cases, there is no legal authority for treating a component of a device with premarket approval differently from the entire device.[2] While citing irrelevant cases, Plaintiffs simply ignore the numerous decisions around the country that have squarely held that "the FDA established specific federal requirements for the Infuse Device, even when the Infuse Protein is used alone." *Angeles v. Medtronic, Inc.*, 863 N.W.2d 404, 412 (Minn. Ct. App. 2015); *accord,*

[2] *Samet v. Proctor & Gamble Co.*, 2013 WL 3124647 (N.D. Cal. 2013), involved neither a medical device nor § 360k(a), and thus offers no support for Plaintiffs' assertion that "[t]here are no FDA requirements applicable to the promotion and use of isolated components of an approved device." Opp. 19. And, if anything, *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694 (W.D. Tenn. 2011), affirmatively *undermines* Plaintiffs' argument because there the court concluded that *Riegel*'s first step was satisfied and that § 360k(a) therefore applied to the plaintiff's claims notwithstanding allegations that the defendant device manufacturer had *deviated from the design* approved by the FDA. *See id.* at 697. Here, by contrast, there is no allegation that Medtronic deviated in any way from the design of Infuse approved by the FDA.

e.g., *Houston*, 957 F. Supp. 2d at 1176 (rejecting "Plaintiff['s] argu[ment] that the PMA process for the Infuse Device only establishes federal requirements for the InFUSE Bone Graft used in conjunction with the LT–Cage, but not the InFUSE Bone Graft used alone"); *see also, e.g.*, *Hafer*, 99 F. Supp. 3d at 858 ("the PMA does impose federal requirements upon the BMP/Sponge"); *Beavers-Gabriel*, 15 F. Supp. 3d at 1033 ("[E]ven though off-label use of only a component of the Infuse Device is at issue, the FDA approval applies 'with respect to' the Infuse Device generally and therefore such approval includes its components."). Indeed, Plaintiffs' assertion that premarket approval of the Infuse device does extend to the device's constituent components cannot be reconciled with the FDCA, which explicitly defines "[t]he term 'device'" to "includ[e] *any component*" of a device. 21 U.S.C. § 321(h) (emphasis added); *see Angeles,* 863 N.W.2d at 411 ("The FDCA's definition of 'device' includes 'any component, part, or accessory.'") (quoting 21 U.S.C. § 321(h)); *accord Hafer*, 99 F. Supp. 3d at 858.[3] Thus, "[t]here is no merit to Plaintiff[s'] assertion that § 360k(a) does not apply because Plaintiff[s'] surgeon[s] supposedly implanted the Infuse device without its LT-Cage component." *Latimer,* 2015 WL 5222644, at *7.

2. PMA requirements attach to devices, not individual uses.

Medtronic has explained that the Fifth Amended Complaint rests on a false premise, *i.e.*, the erroneous assertion that premarket approval applies only to particular *uses* of a device. *See*

[3] It would be illogical if the applicability of § 360k(a)—which is part of a regulatory scheme designed to give the FDA the primary role in oversight of medical devices and to protect manufacturers from different or additional state claims and regulation and thereby induce the development of innovative medical devices—turned on physicians' treatment decisions, over which manufacturers have no control. On Plaintiffs' theory, each time a doctor chooses to use a device in an off-label manner by using less than all of its components or by substituting something in place of one of its components, as each doctor may freely do, the doctor has invented a new device for which there are no federal requirements and thereby stripped the manufacturer of the protections that § 360k(a) provides.

Mem. 9. Plaintiffs' Opposition to the current motion rests on the same error. *See, e.g.*, Opp. 6, 11–13, 25. In support of their contention that premarket approval is use-specific, Plaintiffs offer only their own purported interpretations of certain FDA regulations. In fact, the FDA itself has stated that "[t]he term 'unapproved uses' is … misleading," because the agency does not regulate the use of medical devices. FDA, *Use of Approved Drugs for Unlabeled Indications*, 12 FDA Drug Bull. 4, 5 (1982).

While Congress has empowered the FDA to regulate the design, manufacture, and labeling of Class III devices, it also forbade the FDA from restricting how an approved device may be used, explicitly providing that "[n]othing in [the FDCA] shall … limit … the authority of a health care practitioner to ... administer any legally marketed device … for any condition or disease." 21 U.S.C. § 396; *see also Buckman*, 531 U.S. at 350. Because the FDA has no power to limit approval to particular *uses* of a device, FDA approval establishes requirements that apply to a device in general, no matter how it is ultimately used. As the U.S. Court of Appeals for the Tenth Circuit explained in an opinion affirming the dismissal of claims arising from alleged off-label promotion of the Infuse device, "Congress proceeded in § 360k(a) to preempt any state tort suit challenging the safety of a federally approved device *without qualification about the manner of its use*." *Caplinger II*, 784 F.3d at 1344 (emphasis added); *see also Riley*, 625 F. Supp. 2d at 779; *Hawkins*, 2014 WL 346622, at *6; *Houston*, 957 F. Supp. 2d at 1176.

As the statutory text dictates, the relevant question under § 360k(a) is "not whether there are federal requirements applicable to a particular *use* of a device; the question is whether there are federal requirements applicable 'to the *device*.'" *Latimer*, 2015 WL 5222644, at *7 (quoting *Caplinger v. Medtronic, Inc.* (*Caplinger I*), 921 F. Supp. 2d 1206, 1218 (W.D. Okla. 2013), *aff'd*, 784 F.3d 1335 (10th Cir. 2015), *petition for cert. filed*, 84 U.S.L.W. 3123 (U.S. Sept. 11

2015) (No. 15-321)), in turn quoting *Riley*, 625 F. Supp. 2d at 779). "Nothing depends on whether the plaintiff seeks to use state law to impose requirements for off-label uses or on-label uses." *Caplinger II*, 784 F.3d at 1344. "Rather, by its terms, the statute preempts *any* effort to use state law to impose a new requirement on a federally approved medical device." *Id.*; *see also* Mem. 21–22.

Furthermore, as Medtronic has noted (Mem. 22), Plaintiffs' view that "the Infuse PMA does not establish device-specific federal requirements for" off-label uses, Opp. 20, cannot be reconciled with *Riegel*, the seminal Supreme Court case interpreting § 360k(a) in the context of premarket approval. Although the label of the catheter at issue in *Riegel* stated that it was not to be used in patients with diffuse or calcified stenoses and was not to be inflated above 8 atmospheres of pressure, the catheter was used in a patient with diffuse and calcified stenoses and was inflated to 10 atmospheres. *See* 552 U.S. at 320. Despite the fact that the device at issue in *Riegel* was used in an off-label manner, the Court applied § 360k(a) and held the state-law claims to be preempted. *See id.* at 321–30; *Caplinger II*, 784 F.3d at 1345. Thus, as various courts have recognized, "the suggestion that … § 360k(a) does not apply because Plaintiff's surgeon supposedly used the Infuse device in an off-label manner 'is clearly inconsistent with *Riegel*[,] which also involved the off-label use of a medical device.'" *Latimer*, 2015 WL 5222644, at *7 (quoting *Gavin*, 2013 WL 3791612, at *12).

In arguing that the FDA's grant of premarket approval—and thus the scope of preemption under § 360k(a)—is limited to certain uses, Plaintiffs note that "the FDA did not weight risk versus benefit with regard to the Infuse bone protein *alone*, or for surgeries different than … anterior fusion." Opp. 19–20. But Plaintiffs are wrong to suggest that the FDA did not consider potential off-label uses when deciding to grant premarket approval to the Infuse device.

In fact, the agency's "approval process generally contemplates that approved [devices] will be used in off-label ways." *United States v. Caronia,* 703 F.3d 149, 166 (2d Cir. 2012). Thus, FDA regulations require a manufacturer seeking premarket approval to submit *all* "data ... relevant to an evaluation of the safety and effectiveness of the device ..., including information derived from investigations other than those proposed in the application" (21 C.F.R. § 814.20(b)(8)(ii)), and require the FDA to consider not only the "conditions of use … suggested in the labeling" but also "other intended conditions of use" when determining whether to grant premarket approval (*id.* § 860.7(b)(2)).[4] With respect to Infuse itself, the FDA reviewed data from studies of off-label uses during the premarket approval process, as Plaintiffs implicitly concede. *Cf.* 5th AC ¶¶ 425, 453, 551. Then, following review of this and other data, the FDA required that the Infuse label include various warnings concerning off-label use of the device. In particular, the FDA required that the label warn that the "**InFUSE Bone Graft component must not be used without the LT-Cage**" (Mem. Ex. 2 at 1); that "[t]he safety and effectiveness of the InFUSE Bone Graft component ... used in surgical techniques other than anterior ... approaches have not been established" (*id*. at 4); and that "[w]hen degenerative disc disease was treated by a posterior interbody fusion procedure with cylindrical threaded cages," rather than the tapered LT-Cage, "posterior bone formation was observed in some instances" (*id.*).[5] That the FDA required the Infuse label to contain warnings regarding potential off-label uses of the device is clear evidence

[4] A device's "intended use" can include "uses other than the ones for which [the manufacturer] offers it." 21 C.F.R. § 801.4.

[5] Although legally irrelevant, because their claims would be preempted even if the FDA had not mandated the inclusion of such warnings, the fact that the label specifically addresses off-label use underscores the fact that Plaintiffs' claims would impose "different" or "additional" requirements on the Infuse device.

that, as the statute dictates and numerous courts have held, premarket approval is "not use-specific." *Angeles,* 863 N.W.2d at 411.

3. Allegations of off-label promotion do not affect preemption.

Perhaps recognizing the futility of their argument that preemption turns on how an approved device is *used,* Plaintiffs contend that preemption does not apply in this case because Medtronic purportedly violated federal law by allegedly promoting off-label use of the Infuse device. Opp. 23. This contention fails for several reasons.

First, even if a manufacturer has violated federal law, the premarket approval for the device remains in place and § 360k(a) continues to preempt any state-law claim that would impose requirements "different from, or in addition to" those imposed by federal law. *See, e.g.*, *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 28–29 (1st Cir. 1995); *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694, 697 (W.D. Tenn. 2011).[6]

Second, as Medtronic explained (Mem. 22), Plaintiffs' argument that off-label promotion somehow negates the preemptive effect of premarket approval is inconsistent with the statutory text. "[N]othing in § 360k(a) suggests that the preemption analysis somehow depends on how the device is being promoted to be used." *Caplinger I*, 921 F. Supp. 2d at 1218; *accord, e.g.*, *Scanlon v. Medtronic Sofamor Danek USA, Inc.*, 64 F. Supp. 3d 403, 411 (D. Del. 2014);

[6] Premarket approval is never automatically invalidated. On the contrary, revocation of premarket approval is governed by a detailed statutory and regulatory procedure that requires explicit FDA action. *See, e.g.*, 21 U.S.C. § 360e(e), (g); 21 C.F.R. §§ 10.45, 16.62, 16.80, 16.95, 16.120, 814.46. Revocation of premarket approval requires, among other things, that the FDA "issue an order withdrawing approval," something that can occur only "after due notice" to the manufacturer and, if requested, an "informal hearing" followed by a formal "review," which in turn requires that the agency convene a panel of experts to "submit … a report and recommendation," which "shall [be] ma[d]e public" and which the agency "shall by order" either accept or reject. 21 U.S.C. § 360e(e)(1)–(3), (g)(2). Plaintiff does not—and cannot—allege that the FDA has taken any, let alone each, of the steps that would be necessary for the agency to revoke Infuse's premarket approval.

Hawkins, 2014 WL 346622, at *6; *Gavin*, 2013 WL 3791612, at *11; *Ledet*, 2013 WL 6858858, at *3; *Latimer*, 2015 WL 5222644, at *7; *see also Perez v. Nidek Co.*, 711 F.3d 1109, 1111–13, 1117–19 (9th Cir. 2013) (§ 360k(a) preempts fraud-by-omission claim despite alleged off-label promotion); *Bertini*, 8 F. Supp. 3d at 255 (§ 360k(a) preempts claims notwithstanding allegation manufacturer marketed device for use with component not indicated on its FDA-approved label).[7]

If application of § 360k(a) turned on how a device is promoted, then claims arising from one doctor's unilateral decision to use an approved device in an off-label manner would be subject to § 360k(a), but claims arising from another doctor's decision to make the same use of the same device would *not* be subject to § 360k(a) if that doctor was induced to do so by off-label promotion. That cannot be correct, because application of § 360k(a) depends on "whether the Federal Government has established requirements applicable to [the device]." *Riegel*, 552 U.S. at 321. For any given device at any given time, the federal government either has established requirements or has not. Thus, any suggestion that allegations of off-label promotion renders § 360k(a) inapplicable "is inconsistent with the text of § 360k(a)," (*Gavin*, 2013 WL 3791612, at *11), and "patently illogical" (*Byrnes v. Small*, 60 F. Supp. 3d 1289, 1299 (M.D. Fla. 2015)). Accordingly, "regardless of plaintiff's off-label promotion allegations, each of plaintiff's claims must be analyzed to determine whether it is preempted under § 360k(a)." *Caplinger I*, 921 F. Supp. 2d at 1218.

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[7] Plaintiffs rely (Opp. 23) on *Ramirez v. Medtronic Inc.*, 961 F. Supp. 2d 977 (D. Ariz. 2013), which held that claims predicated on off-label promotion avoid preemption under § 360k(a). But, as Medtronic previously explained (Mem. 22 n.14) and Plaintiffs ignore, "*Ramirez* has been rejected" (*Beavers-Gabriel*, 15 F. Supp. 3d at 1035) by "the majority of other courts" (*Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026, 1036 (D. Ariz. 2014)) as "patently illogical" (*Byrnes v. Small*, 60 F. Supp. 3d 1289, 1299 (M.D. Fla. 2015)) and "not consistent with the text of § 360k(a)" (*Houston v. Medtronic, Inc.*, 2014 WL 1364455, at *5 (C.D. Cal. 2014)).

C. Plaintiffs Have Not Set Forth "Parallel" Claims.

"To state a 'parallel' claim" that escapes preemption under § 360k(a), "a plaintiff must allege (1) the violation of a specific federal requirement applicable to the device; (2) the violation of an identical state-law duty; and (3) that the violation caused his or her injuries." *Millman v. Medtronic, Inc.*, 2015 WL 778779, at *4 n.2 (D.N.J. 2015); *see also* Mem. 23 (collecting cases). As Medtronic has explained (Mem. 23–39), none of Plaintiffs' claims meets that standard.

1. Plaintiffs have not adequately alleged a causal connection between any purported federal violation and their alleged injuries.

In its opening brief, Medtronic argued that Plaintiffs' claims are subject to dismissal because, among other reasons, Plaintiffs have not adequately alleged a causal connection between any purported federal violation and their alleged injuries. *See* Mem. 27–32; 35–39. In their Opposition, Plaintiffs do not deny their failure to adequately allege causation and do not dispute the legal consequence of that failure. "By ignoring th[ese] argument[s], Plaintiff[s] concede[]" them. *Aaron v. Durrani*, 2014 WL 996471, at *7 n.9 (S.D. Ohio 2014); *accord, e.g.*, *Rouse v. Caruso*, 2011 WL 918327, at *18 (E.D. Mich. 2011), *report and recommendation adopted*, 2011 WL 893216 (E.D. Mich. 2011); *Ferdinand-Davenport v. Children's Guild*, 742 F. Supp. 2d 772, 777 (D. Md. 2010); *Hopkins v. Women's Div., Gen. Bd. of Global Ministries*, 284 F. Supp. 2d 15, 25 (D.D.C. 2003), *aff'd*, 98 F. App'x 8 (D.C. Cir. 2004). Plaintiffs' conceded failure to adequately allege that any "predicate federal violation caused [their] injuries" (*Millman*, 2015 WL 778779, at *4 n.2) is fatal to their claims. *See, e.g.*, *Erickson v. Boston Sci. Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011); *see also* Mem. 23 (collecting additional cases).

2. Allegations of off-label promotion do not give rise to a parallel claim.

Plaintiffs' allegations that Medtronic engaged in off-label promotion (*cf.* Opp. 7, 9, 22–23; 5th AC ¶¶ 470–479) do not save their claims from express preemption under § 360k(a). Allegations of off-label promotion would support a parallel claim only if Plaintiffs could show that both federal and state law prohibited the practice. But, as Medtronic demonstrated in its opening brief (Mem. 24–27), Plaintiffs are unable to do so. Nothing in Plaintiffs' Opposition suggests otherwise.

Plaintiffs do not identify any federal statute or regulation that purports to prohibit off-label promotion. Although this Court need not reach the issue—because Plaintiffs' claims are expressly preempted even if federal law did prohibit off-label promotion—Medtronic has identified several recent cases holding that "federal law does not bar off-label promotion." *Schuler v. Medtronic, Inc.*, 2014 WL 988516, at *1 (C.D. Cal. 2014); *see* Mem. 24–25 (collecting cases). Plaintiffs ignore all but one of these cases, *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), which Plaintiffs assert is inapplicable because the Second Circuit noted that "the FDA 'has construed the FDCA to prohibit promotional speech as misbranding itself.'" Opp. 12 n.5 (quoting *Caronia*, 703 F.3d at 155). But Plaintiffs quote *Caronia* out of context. In characterizing the agency's views, the Second Circuit was referring to a draft guidance document from 2009, which, by its own terms, "represent[ed] the [FDA's] current thinking," "d[id] not create or confer any rights for or on any person," "d[id] not operate to bind FDA or the public," and explicitly recognized that manufacturers "may" use an "alternative approach … if such approach satisfies the requirements of applicable statutes and regulations." FDA, Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, 74 F.R. 1694-01 (Jan. 13, 2009). Moreover—as Medtronic noted (Mem. 25) and

Plaintiffs ignore—in *Caronia* itself the Government, speaking on behalf of the FDA, declared that off-label promotion "is not itself a prohibited act under the FDCA, nor … an element of any prohibited act." U.S. Gov't Br. at 51, *Caronia*, 703 F.3d 149, 2010 WL 6351497 (Oct. 8, 2010) (quoted in part in *Caronia*, 703 F.3d at 160).[8] Furthermore, insofar as the prosecution underlying *Caronia* deviated from that declaration and effectively "construed the FDCAs misbranding provisions to prohibit off-label promotion," the Second Circuit explicitly "***decline[d]*** the government's invitation to construe the FDCA's misbranding provisions" in that manner. *Caronia*, 703 F.3d at 162 (emphasis added).[9] Apart from their misplaced reliance on *Caronia*, Plaintiffs have no response to Medtronic's demonstration that federal law does not prohibit off-label promotion.[10]

And, as Medtronic explained (Mem. 25–26), Plaintiff's "claims are preempted even if federal law does prohibit off-label promotion." *Latimer*, 2015 WL 5222644, at *7 n.3. "Whether or not federal law prohibits off-label promotion, Plaintiff[s do] 'not state a parallel state-law

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[8] Plaintiffs also ignore (*cf.* Mem. 25) the Government's subsequent reiteratation that "off-label promotion by a manufacturer is not by itself a violation of federal law" and is "no[t] … among the comprehensive list of prohibited acts in the Food, Drug, and Cosmetics Act." U.S. Statement of Interest, at 1, *United States v. Millennium Pharmaceuticals, Inc.*, No. 2:09-cv-03010 (E.D. Cal.) (Dkt. No. 141) (Mem. Ex. 5). According to the FDA, "the promotion of off-label uses plays" only "an *evidentiary* role in determining whether a [device] is misbranded." U.S. Gov't Br. at 51, *Caronia*, 703 F.3d 149, 2010 WL 6351497.

[9] The Second Circuit's recent decision in *Otis-Wisher*, in which the court unanimously affirmed the dismissal of claims materially indistinguishable from those asserted here, directly undermines Plaintiffs' attempt to avoid *Caronia*. The court—whose panel included Judge Chin, the author of *Caronia*—observed that "[t]he weight of authority both in this Circuit and elsewhere casts doubts on the viability of … claims" that are "premised on allegedly misleading off-label promotion." *Otis-Wisher*, 616 F. App'x at 435 & n.2 (citing, *inter alia*, *Caplinger II*, 784 F.3d at 1341–45, and *Caronia*, 703 F.3d at 162).

[10] Plaintiffs' citation (Opp. 11) to *United States v. Caputo*, 288 F. Supp. 2d 912 (N.D. Ill. 2003) is inapposite. When the Seventh Circuit reviewed that decision, it expressly *refused* to adopt the position Plaintiffs urge. *See* 517 F.3d 935, 940 (7th Cir. 2008) ("[W]e need not decide today whether a seller of … medical devices has a … right to promote off-label uses").

claim' based on off-label promotion as such 'because there is ***no state law duty*** to abstain from off-label promotion.'" *Id.* (emphasis added) (quoting *Thorn v. Medtronic Sofamor Danek USA, Inc.*, 81 F. Supp. 3d 619, 628 (W. D. Mich. 2015)); *see also Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026, 1045 (D. Ariz. 2014); *Beavers-Gabriel*, 15 F. Supp. 3d at 1041; Mem. 26 (collecting additional cases).

In an effort to establish a state-law prohibition on off-label promotion, Plaintiffs argue that state law provides "a cause of action for products liability against a manufacturer which knows or should have known about a risk and fails to provide reasonable warning or instruction regarding the risk." Opp. 25. But—as Medtronic explained (Mem. 26), courts have held, and Plaintiffs ignore—"[a]n affirmative duty to *provide* adequate warnings is not genuinely equivalent to a federal requirement to *refrain* from a particular type of promotion." *Hawkins*, 2014 WL 346622, at *15. Accordingly, the state-law duty to warn is not parallel to, and cannot sustain claims predicated on, a federal duty to not engage in off-label promotion.[11]

3. Allegations that Medtronic failed to report adverse events to the FDA do not give rise to a parallel claim.

Plaintiffs next claim that their failure-to-warn claims avoid express preemption based on their conclusory allegation that Medtronic failed to submit adverse-event reports to the FDA. Opp. 26. Medtronic has already demonstrated in detail the error of Plaintiffs' position (*see* Mem. 32–35), and Plaintiffs' Opposition does not meaningfully engage with Medtronic's analysis or the authorities holding such claims to be expressly preempted by § 360k(a). Rather than refute Medtronic's analysis or distinguish the cases rejecting such claims, Plaintiffs simply

[11] Plaintiffs' allegation that "[t]he Ohio Product Liability Act … does not impose requirements different from or in addition to those imposed by" federal law (Opp. 26) is "a legal conclusion and, as such, [i]s not entitled to the assumption of truth." *Ashcroft v. Iqbal*, 556 U.S. 662, 680 (2009) (quotation marks omitted).

cite a handful of other cases, one of which is derivative of the others, one of which is inapposite, and another of which directly supports Medtronic's position.

Medtronic already explained why two of the cases on which Plaintiffs rely, *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013) (en banc), *cert. denied*, 134 S. Ct. 2839 (2014), and *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011), are wrongly decided. *See* Mem. 35 n.22. A third case on which Plaintiffs rely, *Scovil v. Medtronic Inc.*, 2015 WL 880614 (D. Nev. 2015), adds nothing to the preemption analysis, because the district court which rendered that decision was "bound to apply Ninth Circuit law" as set forth in *Stengel*. *Id.* at *8. And while *McAffee v. Medtronic, Inc.*, 2015 WL 3617755 (N.D. Ind. 2015), concluded that a failure-to-warn claim premised on an alleged failure to file adverse-event reports is not expressly preempted, it relied on *Stengel* and *Hughes* in reaching that conclusion (*see id.* at *5) and is likewise wrongly decided.

Plaintiffs misrepresent the holding in *Hawkins v. Medtronic, Inc.*, 909 F. Supp. 2d 901 (S.D. Ohio 2012) ("*Christopher Hawkins*").[12] Contrary to Plaintiffs' assertion that the court "did not reach the question" whether failure-to-warn claims based on a manufacturer's alleged failure to submit adverse-event reports to the FDA are expressly preempted by § 360k(a) (Opp 26–27), the court squarely held that "[e]ven assuming that Ohio law provides [such] a cause of action …, such a claim would be preempted by the MDA." *Christopher Hawkins*, 909 F. Supp. 2d at 911. And contrary to Plaintiffs' suggestion, *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), does not stand for the proposition that a "failure to warn claim [that] is premised upon Medtronic's [purported] failure to file adverse event reports with the FDA … would not be

[12] To avoid confusion with *Hawkins v. Medtronic, Inc.*, 2014 WL 346622 (E.D. Cal. 2014), an Infuse case, Medtronic will refer to *Hawkins v. Medtronic, Inc.*, 909 F. Supp. 2d 901 (S.D. Ohio 2012), as "*Christopher Hawkins*."

preempted under the MDA." Opp. 26–27. *Bausch*—a manufacturing-defect case—simply does not address, let alone endorse, the proposition that a state law duty to warn patients or their physicians parallels the federal duty to report adverse events to the FDA.[13]

4. Plaintiffs' failure-to-warn claims are expressly preempted.

In its opening brief (Mem. 15–17), Medtronic demonstrated that Plaintiffs' variously styled failure-to-warn claims are expressly preempted by § 360k(a). Medtronic explained that because Plaintiffs do not allege that it failed to provide any of the warnings required by the FDA through the premarket approval process, "[t]he gravamen of each claim is that Medtronic should have provided warnings different from or in addition to those required by the FDA," and that "[a]ny such claim, regardless of the theory under which it is brought, is expressly preempted by § 360k(a)." *Latimer*, 2015 WL 5222644, at *8. Plaintiffs do not dispute this. On the contrary, Plaintiffs explicitly concede that any claim "alleg[ing] that Medtronic's FDA-approved warnings were inadequate under Ohio law … would be preempted." Opp. 26.

Despite that dispositive concession, Plaintiffs advance several arguments in a futile attempt to salvage their failure-to-warn claims. First, Plaintiffs argue that "Section 360k does not apply," and that their claims therefore avoid preemption, given the purported "absence of federal approval of the specific use[s]" of the Infuse device allegedly made by their surgeons. Opp. 23. But, for the reasons discussed above (*see supra* pp. 4–6), "[t]here is no merit to Plaintiff[s'] assertion that § 360k(a) does not apply." *Latimer*, 2015 WL 5222644, at *7. Second, Plaintiffs argue that their various fraudulent failure-to-warns claims survive preemption because they are "based on [Medtronic's alleged] off-label promotion." Opp. 23. But, for the reasons discussed

[13] In any event, as discussed in more detail below (*see infra* pp. 27–28), binding Sixth Circuit authority holds that failure-to-warn claims based on an alleged failure to report adverse events to the FDA are impliedly preempted.

above (*see supra* pp. 13–15), "off-label promotion allegations do not somehow turn plaintiff[s'] claims into 'parallel' claims that are not preempted." *Caplinger I*, 921 F. Supp. 2d at 1218 n.4.[14] Finally, with respect to their strict-liability failure-to-warn claim, Plaintiffs argue that the claim avoids dismissal because it is "premised upon Medtronic's [alleged] failure to file adverse event reports with the FDA." Opp. 26. But, for the reasons discussed above (*see supra* pp. 15–17), "'allegations that Medtronic failed to report adverse events to the FDA do not state a parallel claim'" that escapes preemption under § 360k(a). *Latimer*, 2015 WL 5222644, at *9 (quoting *Cales v. Medtronic, Inc.*, 2014 WL 6600018, at *10 (Ky. Cir. Ct. 2014)). Accordingly, Plaintiffs' failure-to-warn claims are expressly preempted.

5. Plaintiffs' design-defect and implied-warranty claims are expressly preempted.

In its opening brief (Mem. 17–18), Medtronic demonstrated that Plaintiffs' design-defect and implied-warranty claims are expressly preempted by § 360k(a). Plaintiffs offer virtually no argument in response. Notably, Plaintiffs do not dispute that under Ohio law an implied-warranty claim is "virtually indistinguishable from a design defect claim" and that the two claims should be analyzed together. *Tompkin v. Philip Morris USA, Inc.*, 362 F.3d 882, 902 (6th Cir. 2004) (quotation marks omitted) (citing *White v. DePuy, Inc.*, 718 N.E.3d 450, 454 (Ohio Ct. App. 1998)). Nor do Plaintiffs deny that their Complaint fails to allege that the design of the Infuse devices they received was anything other than the design approved by the FDA through the premarket approval process. *Cf.* Mem. 17. Plaintiffs, having tacitly conceded each of these points (*see Aaron*, 2014 WL 996471, at *7 n.9), offer no explanation how their design-defect and

[14] Plaintiffs acknowledge that their fraud claims rest in part on allegations that Medtronic "conceal[ed]" information regarding the safety and effectiveness of the Infuse device. Opp. 22. Yet Plaintiffs do not address, much less rebut, Medtronic's showing (Mem. 15 n.8) that any "fraud by omission claim is expressly preempted by § 360k(a)." *Perez*, 711 F.3d at 1118.

implied-warranty claims can survive express preemption under § 360k(a). In fact, as numerous courts have held, absent an allegation that Medtronic deviated from the device's FDA-mandated design, any design-defect claim is expressly preempted because, "'to prevail on this claim, Plaintiff[s] would need to establish that the Infuse Device should have been designed in a manner different than that approved by the FDA.'" *Latimer*, 2015 WL 5222644, at *9 (quoting *Beavers-Gabriel*, 15 F. Supp. 3d at 1040).[15]

Rather than rebut Medtronic's arguments or address the many cases holding such claims to be expressly preempted (*see* Mem. 17–18 (collecting cases)), Plaintiffs instead offer a litany of largely irrelevant statutes and regulations that they assert "may have been violated by Medtronic." Opp. 28. But Plaintiffs themselves admit that such potential violations are "not specifically pled" in the Complaint. *Id.* "'It is,'" however, "'axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.'" *Watkins v. Conn*, 2015 WL 1927794, at *2 (S.D. Ohio 2015) (quoting *In re Porsche Cars N. Am., Inc.*, 880 F. Supp. 2d 801, 842 (S.D. Ohio 2012), in turn quoting *Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988)).

Moreover, even if the Complaint had alleged violations of the statutes and regulations listed in Plaintiffs' Opposition, Plaintiffs do not—and cannot—explain how such violations could give rise to a cognizable design-defect claim that escaped express preemption under § 360k(a). Indeed, it is unclear how a manufacturer such as Medtronic could ever violate some of the provisions listed in Plaintiffs' Opposition. For example, one of the provisions, 21 U.S.C.

[15] An allegation that Infuse's "design was unsafe when used in the manner promoted by Medtronic" (Opp. 28 (citing 5th AC ¶¶ 6329–6330)) does not save Plaintiffs' design-defect claim. As another court explained when dismissing a design-defect claim arising from alleged off-label promotion of the Infuse device, "'use' is not a 'design'" and a claim based on how the device was "allegedly promoted to be used" is "not a design defect [claim] at all, but rather a failure-to-warn claim." *Cales*, 2014 WL 6600018, at *15 (citing authorities).

§ 360h, delineates the FDA's power to order recalls and take other remedial actions. Another, 21 C.F.R. § 820.1, simply identifies the purpose and scope of certain other regulations, but imposes no requirements of its own. Because these provisions impose no duties on device manufacturers, they could not "have been violated by Medtronic." Opp. 28. And—given that the majority of provisions listed in Plaintiffs' Opposition address manufacturing processes rather than design (*cf.* Opp. 29–30 (listing 21 C.F.R. §§ 820.5, 820.20, 820.22, 820.25, 820.30, 820.70, 820.72, 820.75, 820.80, 820.86, 820.90, 820.100))—it is impossible to understand how a violation of the provisions that might impose duties on device manufacturers could ever give rise to a design-defect claim.

6. Plaintiffs' express-warranty claims are expressly preempted.

Medtronic explained in its opening memorandum (Mem. 18–20) that Plaintiffs' express warranty claims are preempted because, for Plaintiffs to prevail on their warranty claims, a jury would have to find that Infuse "was not safe and effective" as labeled. *Gavin*, 2013 WL 3791612, at *15–16. Plaintiffs do not rebut Medtronic's analysis or attempt to distinguish the many cases holding such claims expressly preempted under § 360k(a).

Instead, Plaintiffs rely principally on *Christopher Hawkins*, which held that an express warranty claim under Ohio law escapes preemption under § 360k(a) because, supposedly, "an Ohio claim for breach of express warranty does not require a finding that the manufacturer's representations are untrue." 909 F. Supp. 2d at 910 (citing *Wagner v. Roche Labs.*, 709 N.E.2d 162, 166 (Ohio 1999) (Cook, J., dissenting)). But neither Plaintiffs nor *Christopher Hawkins* explain how a defendant could be held liable "for ***breach of*** [an] express warranty" (*id.* (emphasis added)) unless the statements giving rise to the purported warranty were untrue. Indeed, in support of their warranty claim, Plaintiffs explicitly allege that Medtronic's purported

"warranties and representations were false in that BMP-2/Infuse was not safe and effective." 5th AC ¶ 6365.

7. Plaintiffs cannot avoid § 360k(a) through evasion of Rule 8(a).

Hoping to avoid dismissal of their Complaint, Plaintiffs repeatedly suggest that dismissal is inappropriate whenever a "complaint has not defined 'the precise contours of [the plaintiff's] theory of recovery'" but nonetheless clearly "'include[s] claims that [Defendant] has … violated FDA regulations.'" Opp. 30 (quoting *Christopher Hawkins*, 909 F. Supp. 2d at 908, in turn quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996))[16]; *see also, e.g.*, Opp. 21, 26, 33. Plaintiffs are mistaken.

Federal Rule of Civil Procedure 8 "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Thus, "conclusory allegations that the defendant violated FDA regulations in the manufacture, labeling, or marketing of the premarket approved medical device are insufficient to state a parallel state-law claim and thereby avoid preemption under § 360k(a)." *Ali v. Allergan USA, Inc.*, 2012 WL 3692396, at *6 (E.D. Va. 2012). Thus, "Plaintiffs cannot simply incant the magic words 'Medtronic violated FDA regulations' in order to avoid preemption." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009), *aff'd sub nom. Bryant v. Medtronic, Inc.*, 623 F.3d 1200 (8th Cir. 2010); *accord, e.g., Caplinger I*, 921 F. Supp. 2d at 1224. Rather, "to avoid preemption, Plaintiff

[16] *Christopher Hawkins* misreads *Lohr* as holding that any complaint that could be construed to allege a federal violation is sufficient to survive a motion to dismiss based on § 360k(a). But, as explained immediately below, even if *Lohr* could be read to support that proposition, the Supreme Court's subsequent decisions in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), squarely foreclose such a result. *See Bass v. Stryker Corp.*, 669 F.3d 501, 509 (5th Cir. 2012) ("[T]o plead a parallel claim successfully, a plaintiff's allegations that the manufacturer violated FDA regulations must meet the *Twombly* plausibility standard").

must sufficiently allege a 'parallel' claim in accordance with general pleading standards." *Franklin v. Medtronic, Inc.*, 2010 WL 2543579, at *8 (D. Colo. 2010), *report and recommendation adopted*, 2010 WL 2543570 (D. Colo. 2010). "To state a 'parallel' claim" that escapes preemption under § 360k(a), "a plaintiff must allege … the violation of a *specific* federal requirement." *Millman*, 2015 WL 778779, at *4 n.2 (emphasis added); *accord*, *e.g.*, *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1300–01 (11th Cir. 2011). Moreover, "'[t]o properly allege parallel claims, the complaint must set forth *facts*'" that, if true, would establish the predicate federal violation. *Franklin*, 2010 WL 2543579, at *8 (quoting *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008)) (emphasis by court).

Ignoring the overwhelming authority to the contrary, Plaintiffs assert that "[t]he better reasoned analysis regarding the specificity required in the context of a design defect claim (or any other claim) and MDA preemption is that a plaintiff need not identify the precise defect or the specific federal regulatory requirements that were alleged[ly] violated in order to comply with Rule 8." Opp. 28 n.8. In support of their assertion, Plaintiffs cite *Waltenburg v. St. Jude Medical, Inc.*, 33 F. Supp. 3d 818 (W.D. Ky. 2014), and the out-of-circuit decision in *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), on which *Waltenburg* relied. Plaintiffs' reliance on *Walternburg* and *Bausch* is misplaced.

Bausch and *Waltenburg* are contrary to *Twombly* and *Iqbal*, which together hold that "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). In holding that a more lenient pleading standard applies when a plaintiff asserts claims involving a device that has received premarket approval, *Bausch* and *Waltenbrug* rest on the proposition that "in the context of Class III medical devices, much of the

critical information is kept confidential as a matter of federal law." *Bausch*, 630 F.3d at 560; *Waltenburg*, 33 F. Supp. 3d at 828. But that is no basis for distinguishing *Twombly* or *Iqbal*. In both *Twombly* and *Iqbal*, the plaintiffs asserted claims that depended on information known only to the defendants.[17] Nevertheless, the Supreme Court held that the plaintiffs were required by Rule 8 of the Federal Rules of Civil Procedure to allege the necessary facts in their respective complaints before obtaining discovery, and directed the dismissal of their complaints for having failed to do so. Thus, Rule 8 and binding Supreme Court precedent applicable to all civil cases preclude a pleading standard—such as that adopted in *Bausch* and *Waltenburg*—that would permit an otherwise insufficient complaint to avoid dismissal simply because of the parties' asymmetric access to information.

Not surprisingly, *Bausch* is an outlier. Among the courts to have addressed pleading standards in cases involving medical devices with premarket approval, *Bausch* has "required the least amount of pleading specificity." *White v. Stryker Corp.*, 818 F. Supp. 2d 1032, 1038 (W.D. Ky. 2011). Even *Waltenburg* recognizes that *Bausch* lies "[o]n one end of the spectrum" and

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[17] In *Twombly*, the plaintiffs claimed, and would ultimately have to prove, that the defendants had agreed to engage in an antitrust conspiracy—a fact for which "'the proof is largely in the hands of the alleged conspirators.'" 550 U.S. at 586 (Stevens, J., dissenting) (quoting *Hosp. Bldg. Co. v. Trs. of Rex Hosp.*, 425 U.S. 738, 746 (1976)). Despite that informational imbalance, the Supreme Court held that the plaintiffs nevertheless were required to allege "enough factual matter (taken as true) to suggest that an agreement was made" (*id*. at 556) and ordered that the plaintiffs' complaint be dismissed for failure to satisfy Rule 8 (*id.* at 570). The same is true of *Iqbal*, which dismissed a *Bivens* action in which the plaintiff was required to "plead and prove that the defendant[s] acted with discriminatory purpose." 556 U.S. at 676. Although the plaintiff had to plead and prove the defendants' mental state, which could be known directly only to the defendants themselves, the Court reaffirmed *Twombly*, holding that Rule 8 requires "more than an unadorned, the-defendant-unlawfully-harmed-me accusation" and that a complaint is subject to dismissal "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct." *Id.* at 678–79. Thus, as the Sixth Circuit has recognized, *Twombly* and *Iqbal* hold that a "plaintiff must allege specific facts … even if those facts are only within the head or hands of the defendants." *New Albany Tractor, Inc. v. Louisville Tractor, Inc.*, 650 F.3d 1046, 1051 (6th Cir. 2011).

"has required the least specificity to plead a claim that will survive a motion to dismiss." *Waltenburg*, 33 F. Supp. 3d at 827.[18]

Indeed, "other courts have rejected *Bausch* as contrary to *Twombly* and *Iqbal*" (*Bertini v. Smith & Nephew, Inc.*, 2013 WL 6332684, at *4 (E.D.N.Y. 2013)), because it condones "precisely the sort of fishing expedition the Supreme Court sought to avoid" (*Ali*, 2012 WL 3692396, at *14) when it held that even under notice-pleading standards a complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level" (*Twombly*, 550 U.S. at 555) and that "Rule 8 … does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions" (*Iqbal*, 556 U.S. at 678–79). There is therefore no merit to Plaintiffs' suggestion that this Court should "den[y] Medtronic's motion to dismiss … due to express preemption pending the results of discovery." Opp. 27. On the contrary, the Supreme Court's admonition that a plaintiff whose "complaint is deficient under Rule 8, he is not entitled to discovery, cabined or otherwise" (*Iqbal*, 556 U.S. at 686) is, as the Sixth Circuit has explained, "binding on the lower federal courts." *New Albany Tractor, Inc. v. Louisville Tractor,*

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[18] *Bausch* was authored by the same judge who wrote *Hofts v. Howmedica Osteonics Corp*., 597 F. Supp. 2d 830 (S.D. Ind. 2009), which held that a manufacturing-defect claim escaped dismissal despite the plaintiff's failure "to specify in his complaint exactly how a product defect occurred." *Id.* at 840–41. But numerous courts have rejected the logic of *Hofts*—and, implicitly, *Bausch*—as inconsistent with Rule 8 and *Twombly*. *See, e.g.*, *Leonard v. Medtronic Inc.*, 2011 WL 3652311, at *6 n.5 (N.D. Ga. 2011) (declining to apply *Hofts*, which "has been criticized by several courts for its lax interpretation of *Twombly*'s standards"); *Gelber v. Stryker Corp.*, 752 F. Supp. 2d 328, 334 (S.D.N.Y. 2010) (rejecting *Hofts* as "unique in applying such a lax pleading standard"); *Anthony v. Stryker Corp.*, 2010 WL 1387790, at *5 (N.D. Ohio 2010) (declining to follow *Hofts* because cases applying higher standard under Rule 8 are "more persuasive") (quotation marks omitted); *Covert v. Stryker Corp.*, 2009 WL 2424559, at *13 (M.D.N.C. 2009) ("*Twombly* requires more from a plaintiff … than the *Hofts* court would demand"); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009) ("The court declines to follow [*Hofts*'s] analysis, and instead follows the larger number of courts that have rejected the sufficiency of pleading nothing more than [a federal] violation … in support of a parallel claim."); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 283 n.5 (E.D.N.Y. 2009) (rejecting the *Hofts* pleading standard and concluding that "requiring amplification as to how the defendants' alleged federal violations relate to the plaintiff's claims is exactly what *Twombly* contemplates").

Inc., 650 F.3d 1046, 1051 (6th Cir. 2011). Thus, as numerous courts have held, Plaintiffs "must successfully plead a claim before obtaining discovery, and not the other way around." *Desai v. Sorin CRM USA, Inc.*, 2013 WL 163298, at *7 (D.N.J. 2013) (collecting cases).

Moreover, even if *Bausch* were controlling law in this Circuit, it would not help Plaintiffs here. Unlike this case, *Bausch* was a manufacturing-defect case. The *Bausch* court thought it appropriate to relax the Rule 8 standards in a manufacturing-defect case because "much of the critical information"—in particular, "[t]he specifications" contained in "the FDA's premarket approval documents"—"is kept confidential as a matter of federal law." 630 F.3d at 560. Here, however, none of Plaintiffs' claims depends on confidential information. Plaintiffs' claims rest on the contention that Medtronic violated the Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations (*see* Opp. 25–26, 28–30; *cf.* 5th AC ¶¶ 483–488), *not* a confidential requirement contained in the Infuse PMA application. The United States Code and the Code of Federal Regulations—which contain the federal requirements on which Plaintiffs' claim rest—are publicly available.[19] Thus, there is no merit to Plaintiffs' suggestion that the Court should excuse their failure to allege "sufficient factual matter, accepted as true, to 'state a claim [for] relief that is plausible on its face.'" *Garcia v. Fed. Nat'l Mortg. Ass'n*, 782 F.3d 736, 739 (6th Cir. 2015) (quoting *Twombly*, 550 U.S. at 570).[20]

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[19] Similarly, Plaintiffs' fraud and warranty claims are necessarily predicated on purported representations by Medtronic that were allegedly *conveyed to Plaintiffs or their surgeons*. *See, e.g.*, 5th AC ¶¶ 6309, 6349, 6365. Unlike the PMA requirements at issue in *Bausch*, such purported representations are not "accessible only to the FDA and the manufacturer." *Bausch*, 630 F.3d at 560.

[20] As another court within this district has recognized, *Bausch* does not save a complaint from dismissal where the complaint does not "provide any factual support for an allegation of … violations of federal law." *Anderson v. Boston Scientific Corp.*, 2013 WL 632379, at *4 n.1 (S.D. Ohio 2013). Indeed, in *Bausch* itself, the "plaintiff did not simply rely on conclusory allegations of a failure to comply with FDA requirements, but was able to cite to an FDA investigation into the approved device, an FDA product recall and a warning letter bearing a causal relationship to

II. PLAINTIFFS' CLAIMS ARE IMPLIEDLY PREEMPTED.

Supreme Court precedent makes "clear that express and implied preemption are not mutually exclusive." *In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig.*, 2004 WL 45503, at *5 (D. Minn. 2004) (citing *Buckman*, 531 U.S. 341). Here, Medtronic demonstrated in its opening brief that Plaintiffs' claims are not only expressly preempted but also impliedly preempted. *See* Mem. 39–46. Specifically, Medtronic showed that (a) Plaintiffs' claims premised on alleged off-label promotion or a purported failure to submit adverse-event reports to the FDA are impliedly preempted under 21 U.S.C. § 337(a) and *Buckman* (Mem. 39–44), and (b) Plaintiff's failure-to-warn, design-defect, and warranty claims are impliedly preempted under traditional conflict-preemption principles (Mem. 45–46). Nothing in Plaintiffs' Opposition casts doubt on those conclusions.

A. Claims Premised On Alleged Violations Of FDA Regulations Are Barred By *Buckman* And 21 U.S.C. § 337(a).

Plaintiffs argue that none of their claims runs afoul of *Buckman* or 21 U.S.C. § 337(a), because their claims, supposedly, are not "state-law-fraud-on-the-FDA" claims. Opp. 27, 30. Plaintiffs' argument misses the mark, both because *Buckman* is not limited to fraud-on-the-FDA claims, and because, even if *Buckman* were so limited, Plaintiffs' claims are effectively fraud-on-the-FDA claims.

The fact that Plaintiffs' claims are nominally state-law claims styled as something other than claims for fraud-on-the-FDA does not remove them from *Buckman*'s reach. The plaintiffs in

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plaintiff's alleged injuries, and to a factual statement by the FDA suggesting that the device in question had not been manufactured in accordance with regulatory standards." *Smith v. St. Jude Med. Cardiac Rhythm Mgmt. Div.*, 2013 WL 1104427, at *4 (D. Md. 2013). Here, as in *Smith*, "Plaintiffs provide no such factual support … for [their] allegation that [Medtronic] failed to comply with FDA requirements," and, "[a]s a result, as pled, Plaintiffs' claims … are not supported by sufficient allegations to constitute a 'parallel claim.'" *Id.*

Buckman "sought damages … under state tort law" for "injuries resulting from the use of" an allegedly unsafe device. 531 U.S. at 343. Thus, there is no material distinction between Plaintiffs' claims, which seek damages under state tort law for injuries allegedly caused by Infuse, and those held impliedly preempted in *Buckman*. Moreover, courts have routinely rejected the suggestion that *Buckman* "only applies to fraud-on-the-FDA claims," holding that "*Buckman* cannot be read that narrowly." *Martin*, 32 F. Supp. 3d at 1034 n.22. On the contrary, "[t]he *Buckman* Court's holding that the FDCA does not provide a private right of action is not limited to the facts of *Buckman*." *Williams v. Zimmer U.S. Inc.*, 2015 WL 4256249, at *6 (E.D.N.C. 2015). Rather, "case law indicates that the *Buckman* Court's holding preempts claims brought based on a failure to disclose a lack of FDA approval and for promotion of off-label use." *Id.* (collecting cases). In fact, state and federal courts across the country have repeatedly read *Buckman* as preempting claims predicated on alleged off-label promotion or a purported failure to submit adverse-event reports to the FDA. *See, e.g.*, *Latimer*, 2015 WL 5222644, at *7, *9 (collecting cases); *see also* Mem. 30–33.

Although none of Plaintiffs' claims is styled a fraud-on-the-FDA claim, allegations of fraud on the FDA permeate each claim. Plaintiffs' fraud and strict-liability claims rest on the allegation that Medtronic "cho[se] not to report to the FDA known adverse events." 5th AC ¶¶ 6305(j), 6345(k). According to Plaintiffs, their negligence claim likewise "is based on Medtronic's [alleged] failure to to report adverse events to the FDA." Opp. 32. In other words, these claims are based on the contention that Medtronic failed to disclose information to the FDA that it purportedly had a duty to disclose. The same is true of Plaintiffs' failure-to-warn claim, which Plaintiffs themselves characterize as based on the alleged violation of a duty that purportedly "extends to third parties like the FDA." Opp. 26 (citing 5th AC ¶ 601 (alleging

"failure to report adverse events")). Thus, these claims are in effect claims of fraud on the FDA. As the Sixth Circuit has held, a claim based on a manufacturer's alleged failure to comply with the FDA's "conditions of approval," which incorporate the FDCA's adverse-event reporting requirements, "is a disguised fraud on the FDA claim." *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005).[21]

Indeed, all of Plaintiffs' claims are thinly veiled fraud-on-the-FDA claims. A central premise underlying each claim is that "Medtronic consciously and deliberately orchestrated a campaign to end-run the FDA's 2002 approval of and labeling for the Infuse device." 5th AC ¶ 517. According to Plaintiffs, Medtronic marketed Infuse for certain off-label uses "[d]espite … lack of FDA approval" for such uses. *Id.* ¶ 329; *see also e.g.*, *id.* ¶ 489 ("Defendants violat[ed] … FDCA statutes and accompanying regulations" by promoting Infuse for off-label uses). Thus, on Plaintiffs' theory of the case, Medtronic was required—yet failed—to obtain FDA approval for uses other than those indicated on the proposed labeling submitted to the FDA during the premarket approval process. *Cf. id.* ¶ 415 ("According to the label sought by Defendants in the PMA and subsequently approved by the FDA …, Infuse can only be used in an ALIF procedure[] involving a single-level fusion in the L4-S1 region of the lumbar spine.").[22] Having allegedly failed to obtain initial FDA approval to market the Infuse device for those other uses, Medtronic was, according to Plaintiffs, "required to"—yet "fail[ed] to"—"submit a supplemental application [to the FDA] for approval of additional uses." Opp. 32 (citing 21 C.F.R. § 814.39). In other words, much like the plaintiffs in *Buckman*, Plaintiffs here assert "state-law causes of

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[21] The record contains a copy of the conditions of approval in effect when the FDA granted premarket approval to the Infuse device; they explicitly reference "[t]he Medical Device Reporting (MDR) Regulation" set forth in 21 C.F.R. § 803.50. *See* Mem. Ex. 1 at 8.

[22] As explained above (*see supra* pp. 6–10), Plaintiffs' Complaint rests on the false premise that premarket approval is use-specific.

action claiming that [a medical-device manufacturer] made fraudulent representations to the FDA as to the intended use of [a spinal device] and that, as a result, the device[was] improperly given market clearance and [was] subsequently used to the plaintiffs' detriment." *Buckman*, 531 U.S. at 346–47. But, as the Supreme Court has explained, *Buckman* holds that 21 U.S.C. § 337(a) impliedly preempts state-law tort claims based on a manufacturer's alleged "failure to properly communicate with the FDA." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2578 (2011). Therefore, there is no merit to Plaintiffs' assertion that their claims "are not impliedly preempted under *Buckman*." Opp. 23.

1. Claims premised on alleged off-label promotion are impliedly preempted.

Plaintiffs do not (and cannot) deny that "the concept of 'off-label use' is a creature of the FDCA, is defined by the FDCA, and is not a part of [state] law." *Caplinger I*, 921 F. Supp. 2d at 1219–20; *see also* Mem. 40 (collecting additional cases). Nor do Plaintiffs deny that, to survive implied preemption under § 337(a), a claim must be premised not only on a traditional state-law duty but on "'the type of *conduct* that would traditionally give rise to liability under state law.'" *Blankenship*, 6 F. Supp. 3d at 986 (emphasis added) (quoting *Caplinger I*, 921 F. Supp. 2d at 1214). It is for these reasons that court after court has held that claims premised on alleged "promotion and marketing of the Infuse device for off-label uses" are "impliedly preempted under *Buckman* and § 337(a)." *Caplinger I*, 921 F. Supp. 2d at 1223; *accord, e.g.*, *Hafer*, 99 F. Supp. 3d at 857; *Latimer*, 2015 WL 5222644, at *7; *see also* Mem. 41 (collecting additional cases). Plaintiffs offer no reason to depart from the weight of well-reasoned authority.

2. Claims premised on an alleged failure to submit adverse-event reports to the FDA are impliedly preempted.

Relying exclusively on out-of-circuit authority, Plaintiffs contend that claims premised on an alleged failure to submit adverse-event reports to the FDA are "not impliedly preempted

under *Buckman*." Opp. 27. But, as Medtronic explained (Mem. 42–43), binding Sixth Circuit authority holds that any claim predicated on an alleged "failure to submit reports to the FDA" is impliedly preempted by § 337(a), as interpreted by *Buckman*, because any such claim would be an impermissible attempt to enforce exclusively federal requirements with no counterpart in state law. *Marsh v. Genetech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012); *see also Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir. 2000) (§ 337(a) constrains "a state's ability to use a federal statute violation as a basis for state tort liability") (quotation marks omitted); Mem. 42–43 (collecting additional cases). Plaintiffs do not distinguish this authority, offer any reason why this Court should take a contrary view of Sixth Circuit caselaw, or dispute that "this Court is bound by Sixth Circuit precedent." *Loza v. Mitchell*, 2011 WL 1236602, at *4 (S.D. Ohio 2011), *aff'd*, 766 F.3d 466 (6th Cir. 2014), *cert. denied*, 135 S. Ct. 2892 (2015); *accord, e.g.*, *Ross v. Abercrombie & Fitch Co.*, 257 F.R.D. 435, 455 (S.D. Ohio 2009). In short, Plaintiffs fail to offer any persuasive reason why this Court should permit them to pursue claims premised on Medtronic's alleged failure to submit adverse-event reports to the FDA—claims that are "impliedly barred by § 337(a)." *McClelland v. Medtronic, Inc.*, 944 F. Supp. 2d 1193, 1200 (M.D. Fla. 2013); *accord Hafer*, 99 F. Supp. 3d at 859.[23]

[23] That a failure-to-warn claim is a "traditional state-law claim[]" (Opp. 2) does not save Plaintiffs' claims from implied preemption. Rather, as Medtronic explained (Mem. 40 n.26) and Plaintiffs do dispute, to avoid preemption under *Buckman* and § 337(a), the specific "*conduct* on which the claim is premised must be the type of *conduct* that would traditionally give rise to liability under state law." *Riley*, 625 F. Supp. 2d at 777 (emphases added); *accord Blankenship*, 6 F. Supp. 3d at 986; *Pinsonneault v. St. Jude Med., Inc.*, 953 F. Supp. 2d 1006, 1017 (D. Minn. 2013); *Caplinger I*, 921 F. Supp. 2d at 1214. Because a failure to submit adverse-event reports to the FDA "is not the type of conduct that would traditionally give rise to liability under state law even if the FDCA had never been enacted," any claim based on such alleged conduct "is impliedly preempted." *Pinsonneault*, 953 F. Supp. 2d at 1017.

B. Plaintiffs' Claims Conflict With Federal Law.

1. Plaintiffs' design-defect, implied-warranty, and failure-to-warn claims are impliedly preempted.

However construed, Plaintiffs' design-defect, implied-warranty, and failure-to-warn claims are impliedly preempted.[24]

If Plaintiffs contend that state law required Medtronic to change Infuse's design or labeling without FDA approval (*cf., e.g.*, 5th AC ¶¶ 6329, 6330), their claims are—as Medtronic explained (Mem. 45) and Plaintiffs ignore—impliedly preempted under traditional conflict-preemption principles, because federal law affirmatively prohibits manufacturers from changing the design or labeling of PMA-approved devices without obtaining prior or ultimate FDA approval. *See* 21 C.F.R. § 814.39; *Riegel*, 552 U.S. at 319.[25]

Plaintiffs' claims are also impliedly preempted if, instead, Plaintiffs contend that Medtronic had a duty to submit to the FDA a PMA Supplement seeking authorization to modify Infuse's design or label. *Cf., e.g.*, Opp. 32 (asserting that under 21 C.F.R. § 814.39 Medtronic was "required to … submit a supplemental application" to the FDA); Opp. 12 ("Because manufacturers may not add new warnings without FDA approval, … manufacturers have an 'obligation to seek a supplemental PMA to add warnings to the label for off-label uses.'"). First, any duty to submit a PMA Supplement "exist[s] solely by virtue of the FDCA" and thus may be enforced only by "the Federal Government rather than private litigants." *Buckman*, 531 U.S. at

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[24] As noted above (at p. 18) and in Medtronic's opening memorandum (at p.17), Plaintiffs' implied-warranty claim is, as a matter of Ohio law, indistinguishable from their design-defect claim.

[25] It is, moreover, plain that a verdict in Plaintiffs' favor on their design-defect claim—which alleges that Infuse "was defectively designed" (5th AC ¶ 6329)—would conflict with the FDA's "'weigh[ing]" of "'any probable benefit to health from the use of the device against any probable risk of injury or illness from such use'" and its conclusive determination that there was "a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 318.

349 n.4, 353. Accordingly, any claim based on that duty is preempted under *Buckman*, which holds that "federal … medical device laws pre-empt[] a state tort-law claim based on [a manufacturer's] failure to properly communicate with the FDA." *Mensing*, 131 S. Ct. at 2578; *accord Pearsall v. Medtronic, Inc.*, 2015 WL 8160888, at *9 (E.D.N.Y. 2015) ("to the extent Plaintiff's claim seeks to enforce an FDA requirement for PMA supplements, that right of enforcement rests solely with the FDA and the claim is impliedly preempted"); *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694, 696 (W.D. Tenn. 2011) ("To the extent that Plaintiffs' claims are based on [the manufacturer's] purported failure to submit a PMA Supplement Application and obtain PMA approval pursuant to 21 C.F.R. § 814.39 …, the claims are impliedly preempted."). Second, the mere submission of a PMA Supplement would not have resulted in the modification of Infuse's design or warning label, as purportedly demanded by state law; any such change would have been dependent on the FDA's approval of the application. *See Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6) and 21 C.F.R. § 814.39(c)). But any state-law claim is impliedly preempted unless the defendant "could *independently* do under federal law what state law requires of it." *Mensing*, 131 S. Ct. at 2579 (emphasis added). The possibility that "the Federal Government *might*" have approved a design or labeling change if Medtronic had submitted a PMA Supplement does not "suffice to prevent federal and state law from conflicting for Supremacy Clause purposes." *Id.* Allowing the imposition of state-law liability based on "conjectures" about what the FDA would have done if a PMA Supplement had been submitted would "render[] … pre-emption all but meaningless" and deprive "the Supremacy Clause [of] any force." *Id.* Thus, "any claim based on Defendants' failure to seek a supplemental PMA would … fail." *Hafer*, 99 F. Supp. 3d at 862.

2. Plaintiffs' warranty claims are impliedly preempted.

In its opening memorandum (Mem. 45–46), Medtronic argued that Plaintiffs' warranty

claims are impliedly preempted, both because "[t]o succeed" on such claims, Plaintiffs would have to "persuade a jury that [the Infuse device is] not safe and effective, a finding that would be contrary to the FDA's approval" of the device (*Bryant*, 623 F.3d at 1207–08), and because warranty claims implicating the safety and effectiveness of a device with premarket approval would require the device "to be safer, but hence less effective, than the model the FDA has approved,'" and would thus "interfere[] with the FDA's regulation of Class III medical devices." *Caplinger I*, 921 F. Supp. 2d at 1213, 1222 (quoting *Riegel*, 522 U.S. at 325). Plaintiffs do not address either argument. "By ignoring th[ese] argument[s], Plaintiff[s] concede[]" them. *Aaron*, 2014 WL 996471, at *7 n.9; *accord, e.g.*, *Rouse*, 2011 WL 918327, at *18; *Ferdinand-Davenport*, 742 F. Supp. 2d at 777; *Hopkins*, 284 F. Supp. 2d at 25.

III. PLAINTIFFS' CLAIMS FAIL ON INDEPENDENT GROUNDS.

In addition to being expressly and/or impliedly preempted, Plaintiffs' claims fail on independent federal and state-law grounds.

A. Plaintiffs' Common Law Claims Are Barred By The Ohio Products Liability Act.

As Medtronic showed in its opening memorandum, the Ohio Products Liability Act ("OPLA") bars each of Plaintiffs' common-law claims. *See* Mem. 46–47. Plaintiffs do not dispute that the OPLA abrogates common-law claims arising from the design, production, or marketing of a product. Instead, Plaintiffs assert that "all [of] their product liability claims … are brought under the [OPLA]." Opp. 26 (citing 5th AC ¶ 323). Tellingly, however, the sole paragraph of the Complaint that Plaintiffs cite in support of this assertion is nothing more than a legal conclusion concerning preemption. *Cf.* 5th AC ¶ 323 (alleging that "OPLA does not impose requirements that are different from or in addition to those imposed by the [FDA]"). Plaintiffs do not—and cannot—identify any claim in their Complaint brought under the OPLA.

B. Plaintiffs' Strict-Liability And Implied-Warranty Claims Are Barred By Comment k To § 402A Of The Restatement (Second) Of Torts.

In its opening memorandum, Medtronic argued (at 47–48) that comment k to Restatement (Second) of Torts § 402A (1965) bars Plaintiffs' strict-liability and implied-warranty claims. Plaintiffs concede that "Ohio has adopted § 402A" and that, where applicable, comment k bars strict-liability and implied-warranty claims. Opp. 34–35. Plaintiffs contend, however, that their strict-liability and implied-warranty claims survive dismissal because "the determination as to whether any particular medical device is 'unavoidably unsafe'" within the meaning of comment k "is necessarily made on a case-by-case basis" and "the Infuse device could be found to *not* be unavoidably unsafe." Opp. 36. But, contrary to Plaintiffs' contention, the Infuse device is "unavoidably unsafe" as a matter of controlling federal law.

That Infuse in particular constitutes an "unavoidably unsafe" product within the meaning of comment k is established by the device's regulatory history, which Medtronic cited (Mem. 48 n.29) and Plaintiffs ignore. Class III devices such as Infuse are, as relevant here, defined as devices that are "for a use which is of substantial importance in preventing impairment of human health, or … present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii). That Infuse in particular "presents a potential unreasonable risk of illness or injury" is evidenced by the fact that the FDA has both designated Infuse a "restricted device" given "its potentiality for harmful effect" (*id*. § 360j(e); Mem. Ex. 1 at 1 (designating Infuse a restricted device pursuant to 21 U.S.C. § 360e(d)(1)(B)(ii)) and categorically determined that the less stringent regulatory controls applicable to Class II devices "are insufficient to provide reasonable assurance of safety and effectiveness for an intervertebral body fusion device when it contains a therapeutic biologic grafting material," as Infuse does. Orthopedic Devices; Reclassification of the Intervertebral Body Fusion Device, 72 Fed. Reg. 32,170, 32,171 (June 12,

2007); *see also* 21 C.F.R. § 888.3080(b)(2) (classifying "intervertebral body fusion devices that include any therapeutic biologic (*e.g.*, bone morphogenic protein)" as Class III devices).

Plaintiffs suggest that it would be "inappropriate to determine at this juncture whether, for the Infuse device, 'there existed no alternative design which would have as effectively accomplished the same purpose or result with less risk,' such that the device can necessarily be said to be 'unavoidably unsafe' under Comment k." Opp. 37 (quoting *White v. Wyeth Labs., Inc.*, 533 N.E.2d 748, 753 (Ohio 1988)). Yet there is no alternative design for Infuse that could lawfully be marketed. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications … that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). There is therefore no grounds for "an in-depth evidentiary inquiry into alternative designs." Opp. 39.

Plaintiffs also contend that comment k does not apply to Infuse because the warnings that Medtronic provided were purportedly inadequate. Opp. 37 ("[P]roper warnings were not properly given."). But this argument too runs headlong into the device's receipt of premarket approval and the FDA's conclusive determination that the warnings contained in the Infuse label *are* adequate. *See Riegel*, 552 U.S. at 319 ("Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in … labeling … that would affect safety or effectiveness.") (citing 21 U.S.C. § 360e(d)(6)(A)(i)). Thus, this attempt to avoid comment k fails for same reasons that Plaintiffs' failure-to-warn claims are expressly and impliedly preempted. *See supra* pp. 17–18, 26–30.

Therefore, Plaintiffs' strict-liability and implied-warranty claims are indeed barred by comment k to § 402A of the Restatement (Second) of Torts. *See Brady v. Medtronic, Inc.*, 2014 WL 1377830, at *6 (S.D. Fla. 2014).[26]

C. Plaintiffs' Warranty Claims Fail.

Medtronic showed that Plaintiffs' warranty claims fails for two reasons: first, Infuse's label disclaimed all warranties; second, Plaintiffs have not adequately pleaded the existence of an express warranty. *See* Mem. 48–51.

1. Medtronic disclaimed all warranties.

Plaintiffs do not deny that Medtronic disclaimed all warranties. Instead, they contend that "since this subject was not mentioned within the Complaint, the topic of disclaimers is not proper in the context of a motion to dismiss." Opp. 33. Plaintiffs are mistaken. As Medtronic demonstrated and Plaintiffs do not dispute, Infuse's FDA-approved label—including its explicit disclaimer of warranties—is judicially noticeable. *See* Mem. 7 n.4. As such, it is properly considered on a motion to dismiss. *See, e.g., Ennenga v. Starns*, 677 F.3d 766, 773 (7th Cir. 2012) ("Taking judicial notice of matters of public record need not convert a motion to dismiss into a motion for summary judgment."); *accord, e.g., Kovac v. Superior Dairy, Inc.*, 930 F. Supp. 2d 857, 862 (N.D. Ohio 2013); *Morris v. Johns Manville Int'l, Inc.*, 2010 WL 3825867, at *1 (E.D. Tenn. 2010). And while an express warranty that forms the basis of the bargain might trump a disclaimer under the laws of some states (*see* Opp. 33 (citing *Scovil.*, 2015 WL 880614, at *12 ("[A]n express warranty overrides a warranty disclaimer under Nevada law.")), this does

[26] Contrary to Plaintiffs' suggestion (Opp. 39), the *Brady* court did not apply comment k merely on the basis of waiver. Although that was one basis for the court's ruling, the court also found "that Infuse is an unavoidably unsafe product that falls within the purview of comment k" "[b]ased on the … case law." 2014 WL 1377830, at *6.

not save Plaintiffs' claim because, as explained immediately below, Plaintiffs have conceded that they have *not* adequately pleaded the existence of an express warranty.

2. Plaintiffs do not adequately allege the existence of an express warranty.

Plaintiffs do not dispute their failure to adequately plead the existence of an express warranty. On the contrary, they explicitly concede that "the express warranties are not pled in detail." Opp. 33. Indeed, the Complaint alleges "*no* supporting facts" that, if true, would establish the existence of an express warranty. *Becker v. Smith & Nephew, Inc.*, 2015 WL 4647982, at *4 (D.N.J. 2015) (emphasis added). Because the Complaint "fail[s] to allege what specific warranty was made," Plaintiffs express-warranty claim must be dismissed. *Schouest v. Medtronic, Inc.*, 92 F. Supp. 3d 606, 609 (S.D. Tex. 2015); *see also* Mem. 50–51 (collecting additional cases).

D. Plaintiffs' Design-Defect Claim Fails Because Plaintiffs Have Not Adequately Alleged A Defect.

As Medtronic demonstrated (Mem. 51), Plaintiffs' design-defect claim fails for the simple reason that Plaintiffs never identify a *defect* in Infuse's *design*. Plaintiffs implicitly concede that have not identified a defect, but argue that they "need not identify the precise defect … in order to comply with Rule 8." Opp. 28 n.8. Indeed, relying on the Seventh Circuit's decision in *Bausch*, Plaintiffs suggest that it would be unreasonable to require them to specify the purported defect "'before discovery.'" *Id.* (quoting *Bausch*, 630 F.3d at 561). Judge Spiegel has considered and rejected this argument:

> Unfortunately for Plaintiffs, discovery cannot be used as a fishing expedition to uncover the facts necessary to support the causes of action presented in the complaint, "even when the information needed to establish a claim ... is solely within the purview of the defendant or a third party." *New Albany Tractor, Inc., v. Louisville Tractor, Inc.*, 650 F.3d 1046, 1051 (6th Cir. 2011). Plaintiffs "may not use the discovery process to obtain facts after filing suit." *Id.* Absent factual support from which the Court may plausibly infer [a design defect], [this count]

> fails to meet the pleading standard set forth by the Supreme Court in *Iqbal* and *Twombly* and must therefore be dismissed.

Anderson v. Boston Sci. Corp., 2013 WL 632379, at *3 (S.D. Ohio 2013) (dismissing design defect claim because plaintiffs "did not allege a single specific … design defect"). This Court should follow Judge Spiegel's reasoning, which reflects not only Sixth Circuit law but the weight of national authority. Under *Twombly* and *Iqbal*, Plaintiffs "must successfully plead a claim before obtaining discovery, and not the other way around." *Desai.*, 2013 WL 163298, at *7 (collecting cases); *see also supra* pp. 24–25.

E. Plaintiffs' Failure-To-Warn Claims Fail For Multiple Reasons.

In its opening memorandum, Medtronic showed two reasons why, in addition to being preempted, Plaintiffs' failure-to-warn claims must be dismissed: first, they are barred by the learned intermediary doctrine; second, Plaintiffs have failed to adequately allege causation. *See* Mem. 51–56. Plaintiffs do not refute either basis for dismissal.

In response to the first point, Plaintiffs argue that their "alleg[ations] that Medtronic intentionally misrepresented and misled the medical community about the risks associated with … off-label use of … Infuse" raise an issue of fact "as to whether the learned intermediary doctrine applies" and that this purported factual issue "precludes dismissal." Opp. 34. But this argument fails for two independent reasons. First, as Medtronic explained (Mem. 53) and Plaintiffs do not contest, Infuse's FDA-mandated label warned of the risk of the very injuries that Plaintiffs allegedly suffered. That label—which also contained various warnings specifically concerning off-label use of the device (*see supra* p. 9)—is adequate as a matter of law. *Cf.* 21 U.S.C. § 360e(d)(1)(A); *Riegel*, 552 U.S. at 329. Second, Plaintiffs' reliance on the Complaint's fraud allegations to avoid application of the learned intermediary rule fails for the same reason

that Plaintiffs' fraud claims fail: the Complaint fails to plead fraud with particularly. *See infra*, pp. 39–41.

In any event, Plaintiffs offer no response to Medtronic's argument that they have failed to adequately allege causation. "By ignoring this argument, Plaintiff[s] concede[] it." *Aaron*, 2014 WL 996471, at *7 n.9. Because the failure to adequately allege causation is fatal to their calims, Plaintiffs' failure-to-warn claims must be dismissed.

IV. PLAINTIFFS FRAUD-BASED CLAIMS ARE NOT ADEQUATELY PLEADED.

In its opening memorandum, Medtronic exhaustively chronicled the myriad ways in which Plaintiffs' fraud-based claims fail:

1) Plaintiffs' fraud allegations are inconsistent and irreconcilable;

2) To the extent that Plaintiffs claim that they, personally, were misled as to the safety of Infuse when used in their respective procedures, they cannot prove causation, because they concede that they had no knowledge, at the time of their respective procedures, that Infuse was even being used;

3) To the extent that Plaintiffs claim that they, personally, were misled by Dr. Durrani as to the safety of Infuse when used in their respective procedures, they cannot connect any alleged misrepresentation to Medtronic, because they have failed to allege facts that, if true, would plausibly suggest that Dr. Durrani was acting as Medtronic's agent when treating patients;

4) To the extent that Plaintiffs claim that that they, personally, were misled as to the safety of Infuse when used in their respective procedures, they have failed to specify the time, place, and content of the alleged misrepresentations made by Medtronic and purportedly received and relied on by them;

5) To the extent that Plaintiffs claim that that Medtronic misled their surgeons, their fraud-based claims fail, because under Ohio law third-party reliance is insufficient to support a fraud-based claim;

6) To the extent that Plaintiffs claim that that Medtronic misled their surgeons, their allegations are insufficient to satisfy Fed. R. Civ. P. 9(b), because they are based on information and belief and hearsay;

7) To the extent that Plaintiffs claim that Medtronic misled their respective surgeons through articles in the medical literature, Plaintiffs have failed to adequately identify any specific article, let alone particular statement within an article, on

which their surgeons allegedly relied;

8) To the extent that Plaintiffs claim that Medtronic misled their respective surgeons through articles in the medical literature, Plaintiffs have failed to adequately allege the falsity of any representation purportedly attributable to Medtronic; and,

9) To the extent that Plaintiffs claim that Medtronic misled their respective surgeons at medical conferences or through sales representatives, Plaintiffs have failed to specify the time, place, content, or speaker of the alleged misrepresentations.

See Mem. 56–85. In the two paragraphs that Plaintiffs devote to defending their fraud-based claims, they do not challenge the second, third, fourth, fifth, sixth, and seventh reasons why these claims fail. *Cf.* Opp. 23–25. "By ignoring th[ese] argument[s], Plaintiff[s] concede[]" them. *Aaron*, 2014 WL 996471, at *7 n.9. Because these ignored arguments are dispositive of Plaintiffs' fraud-based claims, no more need be said. *Id.* But for the sake of a complete record, Medtronic will address what little Plaintiffs do say in their Opposition.

As to Medtronic's first point, Plaintiffs contend generally that "[p]leading in the alternative is needed at this stage of the case." Opp. 41. Anticipating this specious argument, Medtronic showed in its opening memorandum that, although pleading alternative *claims* is permissible, pleading alternative *facts* is not. *See* Mem. 61 (citing cases). Plaintiffs have no response. Plaintiffs' pleading of alternative facts makes it impossible for Medtronic to have fair notice of the grounds upon which Plaintiffs base their fraud-based claims. This does not satisfy Rule 8, let alone Rule 9. *See Twombly*, 550 U.S. at 555.

In response to Medtronic's eighth and ninth points, in which Medtronic showed in detail how each category of representations identified by Plaintiffs—statements made in medical journals, at conferences, and by sale representatives—was insufficiently pleaded (*see* Mem. 71–85), Plaintiffs simply cite paragraphs of the Complaint. *See* Opp. 23–25. But repeating inadequate allegations does not make them adequate, and Plaintiffs do not even attempt to explain why the paragraphs they cite are, contrary to Medtronic's detailed analysis, sufficient to

satisfy Rule 9(b). For example, in response to Medtronic's meticulous demonstration (Mem. 73–83) that Plaintiffs have failed to adequately allege the falsity of any statement identified in the Complaint, Plaintiffs offer nothing more than the conclusory assertion that "[t]he Complaint provides details … why statements made by [purported] Medtronic representatives were false or misleading." Opp. 23. And in response to Medtronic's showing that Plaintiffs have failed to identify any specific statement made at any medical conference, Plaintiffs offer nothing more than the conclusory statement that the Complaint "show[s] the specific content of the [purportedly] false statements." Opp. 24. Because their Complaint "does not allege facts tending to demonstrate the falsity of [any] representations" (*Knight Indus. & Assocs. v. Euro Herramientas, S.A.U.*, 2013 WL 3773373, at *4 (E.D. Mich. 2013)) and "fail[s] to state with particularity which [purported] misrepresentations … their doctors[] relied upon" (*Hafer*, 2015 99 F. Supp. 3d at 859), Plaintiffs have failed to allege fraud "with sufficient particularity, as Rule 9(b) requires." *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006).

CONCLUSION

For all the reasons stated, Plaintiffs' claims should be dismissed.

DATED: December 11, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on December 11, 2015, the foregoing was electronically filed with the Clerk of the Court using the CM/ECF system, which will send a notification to the attorneys of record in this matter. A true and accurate copy of the foregoing document was served via U.S. mail upon the following counsel:

Attorney for Plaintiffs

DATED: December 11, 2015

/s/ James E. Burke
James E. Burke